UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

IN RE: ACTOS DIRECT PURCHASER ANTITRUST LITIGATION THIS DOCUMENT RELATES TO: All Actions	Master File No. 1:15-cv-03278-RA

SECOND CONSOLIDATED CLASS ACTION COMPLAINT AND JURY DEMAND

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I. INTRODUCTION

1. Direct purchaser plaintiffs, American Sales Company, LLC ("ASC") and Cesar Castillo, Inc. ("CCI"), on behalf of themselves and all others similarly situated (the "direct purchasers"), file this Second Consolidated Class Action Complaint and Jury Demand against defendants Takeda Pharmaceutical Company Limited, Takeda America Holdings, Inc., Takeda Pharmaceuticals U.S.A., Inc., and Takeda Development Center Americas, Inc. (collectively, "Takeda"), Mylan Inc. and Mylan Pharmaceuticals, Inc. (collectively, "Mylan"), Actavis plc f/k/a Actavis, Inc. and Watson Laboratories, Inc. (collectively, "Actavis"), Sun Pharmaceutical Industries Limited as successor-in-interest to Ranbaxy Laboratories, Ltd., Ranbaxy, Inc., and Ranbaxy Pharmaceuticals, Inc. (collectively, "Ranbaxy"), and Teva Pharmaceutical Industries, Ltd. and Teva Pharmaceuticals USA, Inc. (collectively, "Teva"). Defendants Mylan, Actavis, Ranbaxy, and Teva will collectively be referred to as "generic defendants." Takeda and the generic defendants will collectively be referred to as "defendants." Based upon personal knowledge as to facts pertaining to them, and upon information and belief as to all other matters, the direct purchasers, through counsel, allege as follows:

2. ACTOS (pioglitazone hydrochloride) is a frequently-prescribed, orally administered glycemic control medication indicated for the improvement of glycemic control in patients with Type 2 diabetes, either as a monotherapy treatment or a combination therapy consisting of two separate drugs—pioglitazone hydrochloride together with sulfonylurea, metformin, or insulin. ACTO*plus* met is indicated as a fixed-dose combination of pioglitazone hydrochloride and metformin to improve blood sugar control in adults with Type 2 diabetes who are either already taking ACTOS and metformin separately or who are taking only

metformin and the metformin alone has not resulted in the needed level of blood glucose control.

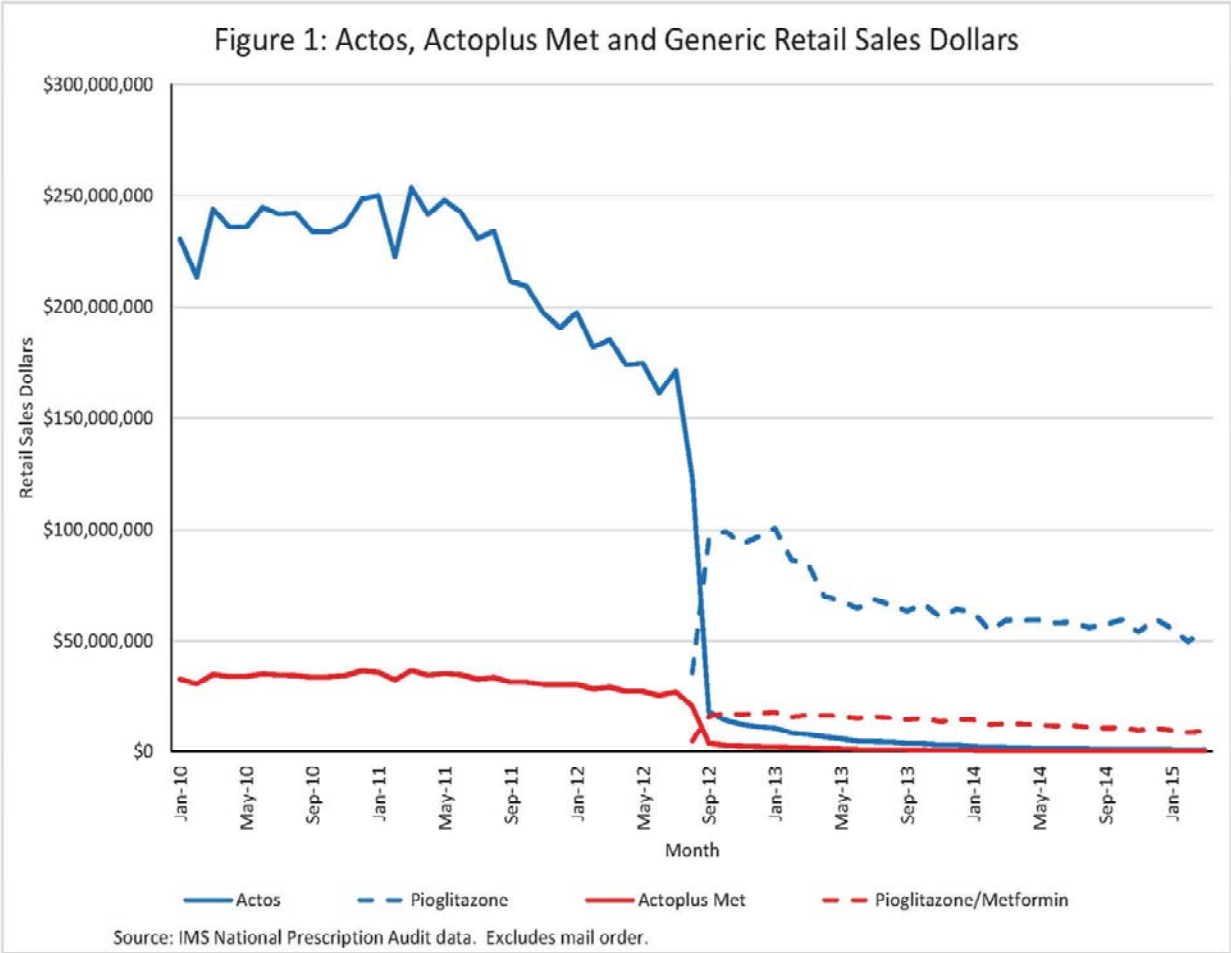
3. At all relevant times, ACTOS was the only pioglitazone hydrochloride available in the marketplace (either as a stand-alone or as a combination therapy, as in ACTO*plus* met). As a result, defendants exacted a supracompetitive price for and made supracompetitive profits on ACTOS sales.

4. This action arises out of an overarching, anticompetitive scheme by brand name drug maker Takeda and, in time, several of its would-be generic competitors to forestall entry of generic competition, and otherwise unlawfully extend monopolies in two related drug markets—the market for pioglitazone hydrochloride tablets (sold by Takeda under the brand name ACTOS) and the market for the fixed dose combination product containing both pioglitazone hydrochloride and metformin (sold by Takeda under the brand name ACTO*plus* met).

5. The amount of money motivating defendants in this case is staggering. Actos was one of Takeda's biggest products. In 2011, Actos generated roughly $3 billion in annual sales in the United States alone.

6. Takeda knew, however, that the products were vulnerable to a rapid and near-complete loss of sales once less expensive generic versions entered the market. ACTOS and ACTO*plus* met were likely to, and did, lose the vast majority of their sales immediately upon generic entry. Figure 1 below provides a pre-discovery estimation of the loss of ACTOS and ACTO*plus* met sales resulting from generic market entry.[1]

[1] All figures are based on reliable pre-discovery industry data.



7. In order to delay the onset of generic competition and squeeze more multi-billion-dollar years out of these products, Takeda devised a multi-part but fully integrated scheme which it enticed its would-be generic competitors to join.

8. *First*, Takeda submitted false and misleading patent information regarding two patents to the Food and Drug Administration (the "FDA") for publication in the *Approved Drug Products With Therapeutic Equivalence Evaluations* (the "Orange Book") with respect to ACTOS. Takeda asserted in its patent information that the two patents – United States Patent Nos. 5,965,584 (the "'584 Met Combo Patent") and 6,329,404 (the "'404 Insulin Combo Patent") – claim the ACTOS drug product when, in fact, both patents plainly and unambiguously do not

claim the ACTOS *drug product*. The '584 Met Combo Patent only claims a *method of using* pioglitazone hydrochloride with metformin, and a drug product consisting of pioglitazone hydrochloride *and* a biguanide. The '404 Insulin Combo Patent claims a *method of using* pioglitazone hydrochloride with insulin, and a drug product consisting of pioglitazone hydrochloride *and* an insulin secretion enhancer. While each patent might claim a particular *method of using* ACTOS, neither claims the drug product ACTOS itself. This distinction, as will be explained, has sweeping consequences for the ability of generics to get to market timely and in a manner contemplated by federal law.

9. The ACTOS drug product contains neither biguanide nor an insulin secretion enhancer, and thus neither the '584 nor the '404 patent claims the ACTOS drug product. Indeed, Takeda has listed the '584 patent in the Orange Book as claiming the drug product ACTO*plus* met, which *does* contain both pioglitazone hydrochloride and a biguanide, and has listed the '404 patent in the Orange Book as claiming the drug product Duetact, which *does* contain both pioglitazone hydrochloride and an insulin secretion enhancer.

10. Among other intended anticompetitive effects, Takeda's submission of false and misleading patent information regarding the '584 Met Combo Patent and '404 Insulin Combo Patent for ACTOS was trying to frustrate the ability of generics to use a section viii statement in order to get to market with a generic ACTOS for non-infringing uses. Another anticompetitive consequence was that the wrongful listing permitted the first generic manufacturer that filed an Abbreviated New Drug Application ("ANDA") with a paragraph IV certification[2] to claim the 180-day exclusivity provided by the Hatch-Waxman Act. That exclusivity prevented the FDA from approving any other ANDAs for generic ACTOS products

[2] 21 U.S.C. § 355(j)(2)(A)(vii)(IV).

for entry into the market until 180 days after the first-filers entered. Takeda's submission of false and misleading patent information thus created a "bottleneck" on FDA approval of *any* generic ACTOS products until the first generic filer entered the market. Later-filing generic manufacturers were automatically delayed due to the first-filer's 180-day exclusivity.

11. Takeda's wrongful Orange Book listing violates Sherman Act §2, regardless of whether the later settlement agreements are anticompetitive (though, here, they are).

12. *Second*, Takeda exacerbated the economic harm caused by its false and misleading patent submission by leveraging the false 180-day exclusivity to incentivize the generic first-filers to delay their generic entry. Takeda reached a coordinated group of anticompetitive agreements with Mylan, Ranbaxy, and Actavis in March of 2010 (the "March 2010 pact").

13. Generic competition for ACTOS was likely to begin immediately after ACTOS's drug substance patent – U.S. Patent No. 4,687,777 (the "'777 ACTOS Compound Patent") – expired on January 17, 2011. Without regard to whether the lawsuits had legal merit, Takeda sued every manufacturer that sought FDA approval to sell generic ACTOS even though many of them had carved out the use of their generic ACTOS with either metformin or insulin.

14. Defendants Mylan, Ranbaxy, and Actavis had all submitted paragraph IV certifications with respect to the '584 Met Combo Patent and the '404 Insulin Combo Patent. Due to the false Orange Book listings for those patents, each was entitled to "shared" 180-day exclusivity for ACTOS. These defendants obtained a June 2010 trial date for their allegations that Takeda's patents allegedly covering ACTOS were invalid, unenforceable, or would not be infringed by their generic products. That trial date would have permitted Mylan, Ranbaxy, and/or Actavis to successfully conclude the patent litigation and enter the market on or about

January 17, 2011, upon expiration of the '777 ACTOS Compound Patent – the only Orange Book-listed patent for ACTOS that actually covered ACTOS.

15. Takeda knew there was a substantial risk that its infringement claims would not prevail in the litigation. Therefore, as the trial date approached, Takeda entered into a joint agreement, herein the "March 2010 pact," with all three of Mylan, Ranbaxy, and Actavis to share the supracompetitive profits made possible by the absence of generic competition in exchange for Mylan, Ranbaxy, and Actavis' agreement to delay entering the market with generic ACTOS products until August 17, 2012. As planned, these arrangements delayed the date of generic entry far beyond January 17, 2011, and had the intended effect of extending the bottleneck on FDA approval of many additional generic manufacturers, all of which were prevented from entering the market until 180 days after August 17, 2012.

16. Under the March 2010 pact, Takeda and the first wave generics solidified the undeserved 180-day exclusivity for ACTOS generics, agreed to share the anticompetitive profits amongst only themselves (and later Teva) from that exclusivity, and entered into below market rate "royalty" agreements with Ranbaxy and Actavis. They also coordinated entry dates in order to dissuade Teva from continuing its section viii approach to generic entry.

17. Takeda repeated this same type of agreement with respect to ACTO*plus* met. Takeda had listed the '584 Met Combo Patent as a drug product patent claiming ACTO*plus* met, and had listed various other patents as applicable method-of-use patents. Without regard to whether the lawsuits had legal merit, Takeda sued every manufacturer that sought FDA approval to sell generic ACTO*plus* met. Defendant Mylan submitted the first ANDA with a

paragraph IV certification with respect to ACTO*plus* met and was thus eligible for the Hatch-Waxman Act 180-day exclusivity.[3]

18. Takeda knew there was a substantial risk that its infringement claims under these patents would not prevail in the litigation. Therefore, Takeda negotiated an anticompetitive agreement to have Mylan retain the falsely created 180-day exclusivity for ACTOS generics in exchange for Mylan agreeing to delay entering the ACTO*plus* met market until 2012. As planned, this delayed entry by the first-filer had the intended effect of extending the bottleneck on FDA approval of many additional generic manufacturers, all of which were prevented from entering the market until 180 days after Mylan entered.

19. Takeda, Mylan, Ranbaxy, and Actavis took additional anticompetitive measures to ensure that defendant Teva did not unravel the anticompetitive schemes they had concocted. Teva had not submitted a paragraph IV certification with respect to the '584 Met Combo Patent and '404 Insulin Combo Patent regarding ACTOS. Instead, Teva filed what is known as a "Section viii statement"[4] attesting that Teva did not seek FDA approval for a use covered by the patents that Takeda had listed in the Orange Book.

20. Without regard to whether the lawsuit had legal merit, Takeda sued Teva for infringement of the patents allegedly covering ACTOS and ACTO*plus* met. Had Teva prevailed in that lawsuit, it could have entered the market with generic ACTOS upon the expiration of the '777 ACTOS Compound Patent on January 17, 2011. Under the Hatch-Waxman Act, and pursuant to the relief that Teva sought in its counterclaims against Takeda, Teva would not have been subject to the 180-day exclusivity bottleneck that Takeda, Mylan,

[3] Plaintiffs do not contend that Mylan's ACTO*plus* met exclusivity was false or otherwise improper.

[4] *See* 21 U.S.C. § 355(b)(2)(B) & 21 U.S.C. § 355(j)(2)(A)(viii).

Ranbaxy, and Actavis had constructed and extended. Teva, like Mylan, Ranbaxy, and Actavis, had secured a June 2010 trial date, which gave it time to obtain a favorable ruling before January 17, 2011.

21. *Third*, and as planned, Takeda leveraged the March 2010 pact to reach a similarly anticompetitive deal with Teva to have Teva withdraw its challenge to the patents and drop its section viii approach (the "December 2010 pact"). In exchange for Teva's agreement to join the delayed entry dates reached by the first wave generics, the December 2010 pact permitted Teva (and Teva only) to join in the false oligopoly created for the first six months of ACTOS generics, and join the exclusivity for ACTO*plus* met. Each license was on below-market-rate royalty terms, and neither had any procompetitive benefit (as authorized generics would otherwise have been on the market in any event).

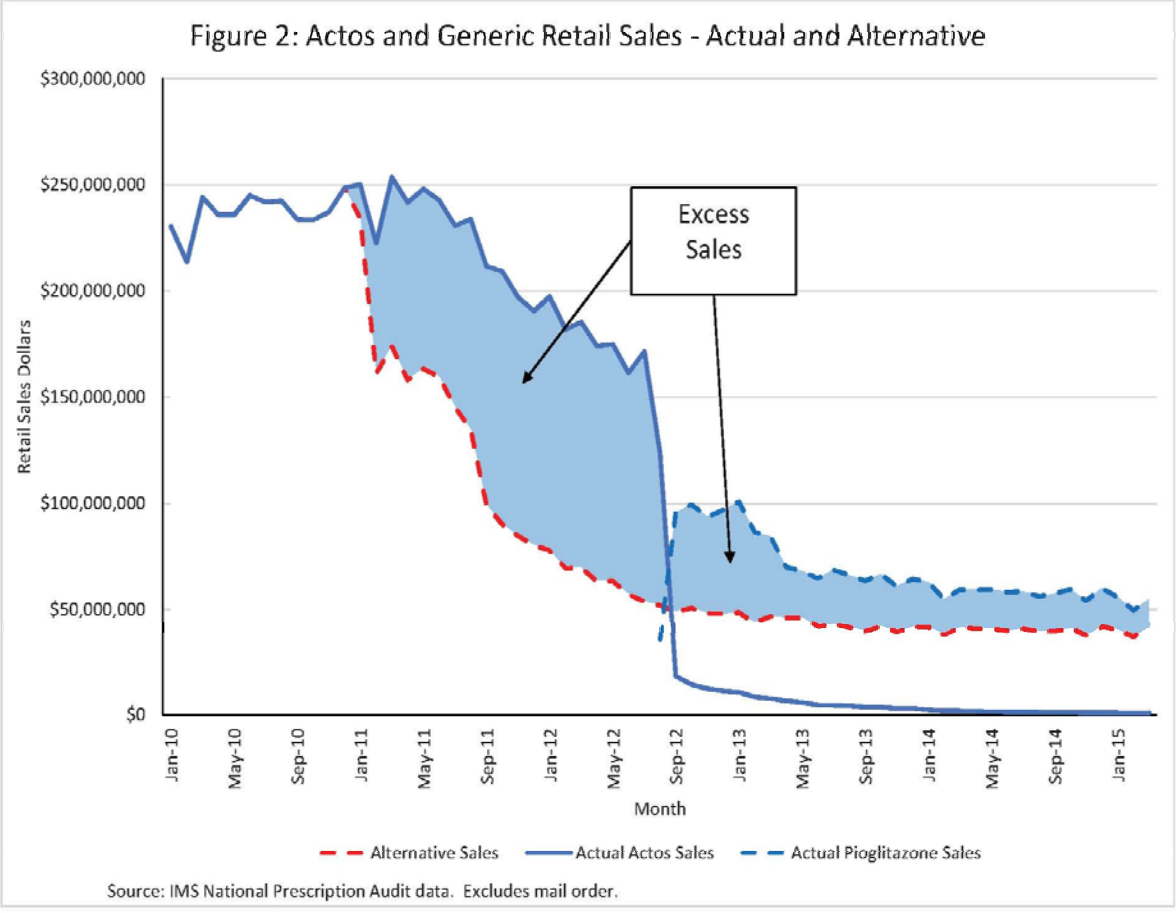
22. Each of the first wave generics and, later, Teva signed on to agreements in which they perpetuated an ACTOS exclusivity to which they were not entitled as a matter of fact and law. And in doing so, they each agreed to join Takeda's unlawful acquisition or maintenance of market power by agreeing to share it with Takeda.

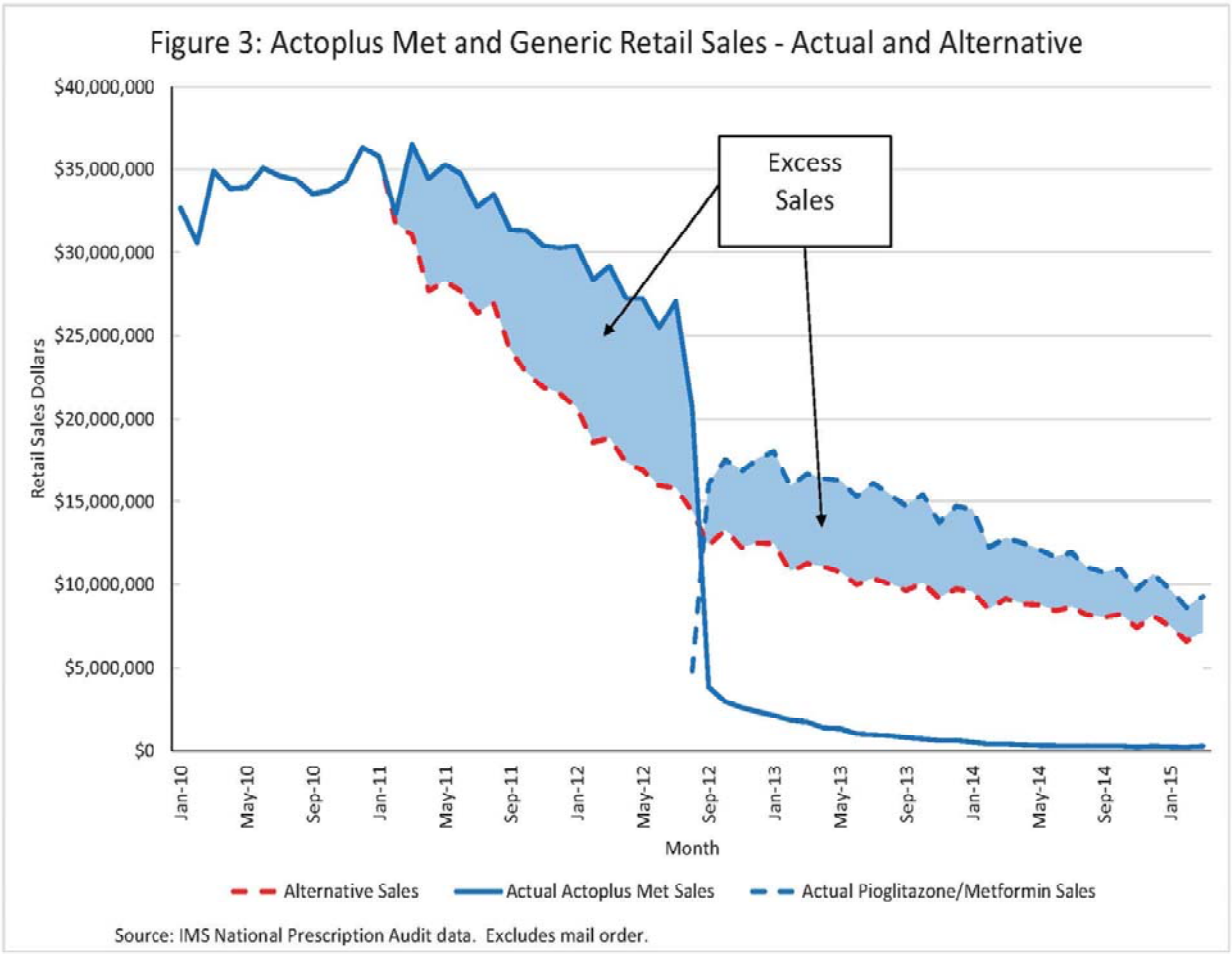
23. Both pacts are market allocation agreements among competitors, and -- independent of any reverse payment theory -- are illegal under traditional rule-of-reason anticompetitive licensure law that existed well before *Actavis* and its reverse payment articulation. That said, the pacts also include large and unjustified payments that run afoul of *Actavis*; reasonable estimations of the size of those payments are detailed below.

24. The defendants' unlawful conduct was designed to and did in fact: (a) delay the entry of less expensive generic versions of ACTOS in the United States; (b) fix, raise, maintain, or stabilize the price of ACTOS and its generic equivalents; (c) permit Takeda to maintain a

monopoly in the United States for ACTOS and its generic equivalents; (d) allocate 100% of the United States market for ACTOS and its generic equivalents to Takeda; (e) delay the entry of less expensive generic versions of ACTO*plus* met in the United States; and (f) fix, raise, maintain, or stabilize the price of ACTO*plus* met and its generic equivalents. Through the unlawful scheme, Takeda and its would-be generic competitors split the unlawfully-extended monopoly profits to the detriment of consumers.

25. The defendants' schemes allowed them to make many hundreds of millions of dollars in unlawful excess sales (*i.e.*, overcharges). The shaded sections in Figures 2 and 3 below provide pre-discovery estimations of the level of overcharges suffered by plaintiffs and the class.





26. The plaintiffs bring this action as a class action on behalf of all direct purchasers who directly purchased branded and/or generic ACTOS and/or ACTO*plus* met products since January 17, 2011 with respect to ACTOS and since February 25, 2011 with respect to ACTO*plus* met (*see* class definitions below).

27. The plaintiffs assert claims for compensatory and/or treble damages for violations of the laws enumerated below.

II. JURISDICTION AND VENUE

28. This action arises under Sections 1 & 2 of the Sherman Act, 15 U.S.C. §§ 1 and 2, and Section 4 of the Clayton Act, 15 U.S.C. § 15(a). The plaintiffs seek damages for their injuries, and those suffered by members of the direct purchaser class, resulting from the defendants' fraudulent and anticompetitive conduct and scheme that delayed the entry of generic drugs into the United States market.

29. The Court has subject matter jurisdiction under 28 U.S.C. §§ 1331, 1337(a), 1367, and 1407, and 15 U.S.C. § 15. This Court also has jurisdiction over this matter under 28 U.S.C. § 1332(d) because this action is a class action in which the aggregate amount in controversy for each of the proposed classes exceeds $5,000,000, and at least one member of each of the putative classes is a citizen of a state different from that of one of the defendants.

30. The defendants are subject to personal jurisdiction in this Court, including general and specific jurisdiction.

31. This Court has general jurisdiction over each defendant because one or more of the defendants has engaged in such a continuous and systematic course of business in this District as to render it at home in New York, sufficient to satisfy both C.P.L.R. § 301 and the requirements of due process. Such course of business includes, but is not limited to:

a. One or more of the defendants has employees, offices and/or facilities in New York;

b. One or more of the defendants actively solicits business in and derives substantial sales and revenue from New York;

c. One or more of the defendants has substantial and ongoing business relationships with New York customers, employees and/or companies; and

d. One or more of the defendants is registered with the New York State Department of State to do business in New York, as a so-called foreign corporation.

32. This Court has specific jurisdiction over each defendant because one or more of the defendants purposefully directed its unlawful anticompetitive activities in New York and this lawsuit results from injuries that arise out of and relate to those New York activities, sufficient to satisfy both C.P.L.R. § 302 and the requirements of due process. Such New York activities include, but are not limited to, those relating to the unlawful agreements that are the subject matter of this action and which: (i) were negotiated, in part, here in New York, (ii) arose out of and resulted in the termination of underlying patent litigation that was pending here in this District; (iii) established that New York law governs their construction; and (iv) provide that the defendants consented to the jurisdiction of this Court in connection with any action arising out of or in connection with these agreements.

33. One or more of the defendants sold the pharmaceutical products at issue in New York at supra-competitive prices, received substantial revenue from the sale of these products in New York and therefore reaped the benefits of its conduct from New York.

34. One or more of the defendants agreed to the jurisdiction of this Court in the underlying patent litigations.

35. Venue is appropriate in this district under 28 U.S.C. §1391(b) and (c) because each defendant resides, transacts business, is found, or has agents within this district, and the interstate trade and commerce described herein is carried out, in substantial part, in this district. Venue is appropriate within this district under section 12 of the Clayton Act, 15 U.S.C. § 22 (nationwide venue for antitrust matters), section 4 of the Clayton Act, 15 U.S.C. § 15(a), and 28 U.S.C. § 1391(b), (c), and (d) (general venue provisions).

III. PARTIES

A. Plaintiffs.

36. Plaintiff American Sales Company, LLC ("ASC") is a Delaware limited liability company with its principal place of business in Lancaster, NY. ASC brings this action on its own behalf and as an assignee of McKesson Corporation which, during the relevant period, purchased ACTOS and ACTO*plus* met directly from its manufacturer, and as a representative of all entities similarly situated. ASC suffered and continues to suffer antitrust injury as a result of defendants' unlawful conduct.

37. Plaintiff Cesar Castillo, Inc. ("CCI") is a corporation organized under the laws of the Commonwealth of Puerto Rico, with its principal place of business located at Bo. Quebradas Arena, Rd. #1 Km. 26.0, Río Piedras, Puerto Rico, 00926. During the relevant period, CCI purchased pioglitazone hydrochloride products directly from defendants at supracompetitive prices and suffered antitrust injury and damages as a result.

38. ASC and CCI are sometimes collectively referred to as the plaintiffs.

B. Defendants.

39. Defendant Takeda Pharmaceutical Company Limited is a Japanese company with its principal place of business at 1-1, Doshomachi 4-chome, Chuo-ku, Osaka 540-8645, Japan.

40. Defendant Takeda America Holdings, Inc. is a wholly-owned subsidiary of defendant Takeda Pharmaceutical Company Limited, and is the United States parent corporation of defendants Takeda Pharmaceuticals U.S.A., Inc. and Takeda Development Center Americas, Inc. Defendant Takeda America Holdings, Inc. is a corporation organized

under the law of the State of New York with its principal place of business at 767 Third Avenue, New York, New York 10017.

41. Defendant Takeda Pharmaceuticals U.S.A., Inc., formerly known as Takeda Pharmaceuticals North America, Inc., is a corporation organized under the laws of the State of Delaware with its principal place of business at One Takeda Parkway, Deerfield, Illinois 60015.

42. Defendant Takeda Development Center Americas, Inc., formerly known as Takeda Global Research and Development Center, Inc., is a corporation organized under the laws of the State of Delaware with its principal place of business at One Takeda Parkway, Deerfield, Illinois 60015.

43. The foregoing Takeda defendants will collectively be referred to as "Takeda."

44. Defendant Mylan, Inc., formerly known as Mylan Laboratories, Inc., is a corporation organized under the laws of the Commonwealth of Pennsylvania with its principal place of business at 1500 Corporate Drive, Canonsburg, Pennsylvania 15317.

45. Defendant Mylan Pharmaceuticals, Inc. is a corporation organized under the laws of the State of West Virginia with its principal place of business at 781 Chestnut Ridge Road, Morgantown, West Virginia 26505.

46. The foregoing Mylan defendants will together be referred to as "Mylan."

47. Defendant Actavis plc is incorporated under the laws of Ireland, with its principal place of business at 1 Grand Canal Square, Docklands Dublin 2, Ireland, and its United States place of business in Morris Corporate Center III, 400 Interpace Parkway, Parsippany, New Jersey 07054. Watson Pharmaceuticals, Inc. changed its name to Actavis, Inc. as a result of Watson Pharmaceuticals, Inc.'s acquisition of Swiss-based Actavis Group in

or around October 2012. On or about October 1, 2013, Actavis, Inc. changed its name to Actavis plc.

48. Defendant Watson Laboratories, Inc. was a Nevada corporation, having its principal place of business at 311 Bonnie Circle, Corona, California. Defendant Watson Laboratories, Inc. was a wholly-owned subsidiary of Watson Pharmaceuticals, Inc.

49. The foregoing Actavis-Watson defendants will together be referred to as "Actavis."

50. Defendant Ranbaxy Laboratories Limited ("Ranbaxy Labs") was a corporation that, until March 25, 2015, was organized and existed under the laws of India, with a principal place of business located at Plot 90, Sector 32, Gurgaon -122001 (Haryana), India. Ranbaxy Labs was the parent company to the entire Ranbaxy business empire, which was, until March 2015, the largest generic drug manufacturer in India. It controlled manufacturing, research, and development, as well as the conduct and functioning of its Indian-based facilities, including a facility located at Paonta Sahib, India.

51. Defendant Ranbaxy, Inc. is a corporation that is organized and exists under the laws of the State of Delaware, and has a place of business located at 600 College Road East, Princeton, New Jersey, 08540. Ranbaxy Inc. was responsible for (a) communications with the FDA on behalf of Ranbaxy Labs and its related entities; (b) prosecution of ANDAs on behalf of Ranbaxy Labs; and (c) management of U.S. litigation on behalf of Ranbaxy Labs and its related entities. At all relevant times, Ranbaxy, Inc. acted in its own right and as an agent of defendant Ranbaxy Labs.

52. Defendant Ranbaxy Pharmaceuticals, Inc. is a wholly-owned subsidiary of defendant Ranbaxy, Inc. Defendant Ranbaxy Pharmaceuticals, Inc. is a corporation organized

under the laws of the State of Delaware with its principal place of business at 600 College Road East, Suite 2100, Princeton, New Jersey 08540.

53. Defendant Sun Pharmaceutical Industries Limited ("Sun Pharma") is a public limited company incorporated under the laws of India with its registered office at Sun Pharma Advanced Research Centre (SPARC), Tandalja, Vadodara – 390 020, Gujarat, India and its corporate office is at Acme Plaza, Andheri Kurla Road, Andheri (East), Mumbai – 400 059, Maharashtra, India. Sun Pharma is an international, integrated, specialty pharmaceutical company. Pursuant to a Scheme of Arrangement between Ranbaxy Labs and Sun Pharm approved by the two companies' boards on April 6, 2014, and completed on or about March 25, 2015, Ranbaxy Labs was merged into Sun Pharma, and all liabilities of Ranbaxy Labs, including contingent liabilities, have been transferred to and vested in Sun Pharma.

54. The Scheme of Arrangement approved by the companies and pursuant to which the merger took place provides that:

> All the liabilities including all secured and unsecured debts, (whether in Indian rupees or foreign currency), sundry creditors, contingent liabilities, duties, obligations and undertakings of [Ranbaxy Laboratories Limited] of every kind, nature and description whatsoever and howsoever arising, raised or incurred or utilized for its business activities and operations (the "Liabilities") shall, without any further act, instrument or deed, be and the same shall stand transferred to and vested in or deemed to have been transferred to and vested in the Transferee Company without any further act, instrument or deed, along with any charge, lien, encumbrance or security thereon….

55. On May 6, 2014, Sun Pharma and Ranbaxy Labs provided notice of the proposed merger to the Competition Commission of India. After investigating the proposed merger, the Commission approved the proposed merger on December 5, 2014, subject to the companies' divesture of certain products. Sun Pharma and Ranbaxy Labs also agreed to divest Ranbaxy

Labs' generic minocycline tablets to Torrent Pharmaceuticals, in response to a complaint brought by the United States Federal Trade Commission.

56. Sun Pharma completed its acquisition of Ranbaxy on or about March 25, 2015 and now owns Ranbaxy. Ranbaxy Labs is no longer listed on the Indian Stock Exchanges.

57. The foregoing defendants Ranbaxy Labs, Ranbaxy Inc., and Ranbaxy Pharmaceuticals, and Sun Pharma are referred to herein as "Ranbaxy."

58. Defendant Teva Pharmaceutical Industries, Ltd., one of the largest pharmaceutical companies in the world, is headquartered in Petah Tikva, Israel.

59. Defendant Teva Pharmaceuticals USA, Inc. is an indirect, wholly-owned subsidiary of Teva Pharmaceutical Industries, Ltd. Defendant Teva Pharmaceuticals USA, Inc. is a corporation organized under the laws of the State of Delaware with its principal place of business at 1090 Horsham Road, North Wales, Pennsylvania 19454.

60. The foregoing Teva defendants will together be referred to as "Teva."

61. All of defendants' wrongful actions described in this complaint are part of, and in furtherance of, the anticompetitive scheme and anticompetitive agreements (as further described below), and were authorized, ordered, and/or executed by defendants' various officers, agents, employees, and/or other representatives while actively engaged in the management of defendants' affairs (or that of their predecessors-in-interest) within the course and scope of their duties and employment, and/or with defendants' actual, apparent, and/or ostensible authority.

IV. INDUSTRY BACKGROUND

62. Branded drug companies can, and do, obtain valid patents that cover their new prescription drug products. Such patents encourage discovery and development of new

medicines, providing protection from competition by other drug companies for a length of time set under a statute by Congress.

63. Once the lawful periods of exclusivity expire on brand products, generic companies can seek FDA approval to sell generic versions of the brand, allowing the generic companies to manufacture generic products that are just as safe and effective, but far less expensive than the brand. The medication becomes affordable for all, and purchasers are no longer burdened by the high cost of the brand drug.

64. Brand companies are required to provide information about which patents cover a particular drug product to the FDA; the FDA then must rely, completely, on the information provided by the brand and list those patents publicly, so that generics understand the scope of the brand's ostensible patent protection. Generics must then make certifications based on the patent information provided by the brand, certifications that affect when their less-expensive products are approved.

65. At root, then, is a basic principle in the American system of access to prescription drugs that addresses these goals and paves the way for both new and more affordable drugs: Branded drug companies have a statutory period of time to charge very high prices for medications that, in fact, cost little to manufacture. But it is a limited period, after which generic companies can compete with low-cost substitutes. And the timing of generic approvals depends on, among other things, the patent information provided by the brand.

66. From this basic principle emerges a rule: Drug companies cannot provide false or misleading patent information in order to set in motion a chain of events that unlawfully delays entry of less expensive, but therapeutically equivalent, generic medications beyond the expiration of legitimate patent protection.

A. The regulatory structure for approval of generic drugs, listing patent information in the Orange Book, and the substitution of generic drugs for brand name drugs.

67. Under the Federal Food, Drug, and Cosmetic Act ("FDCA"), branded drug manufacturers who wish to sell a new drug product must obtain FDA approval by filing a New Drug Application ("NDA").[5] An NDA must include specific data concerning the safety and effectiveness of the drug, as well as information on any applicable patents.[6]

68. The FDA may not approve an NDA if the data and test results provided fail to show that the drug is safe or if there is a lack of substantial evidence that the drug will be effective to treat the conditions suggested in the proposed labeling. The FDA approves new drugs based on their ability to satisfy the minimum regulatory requirements; namely, show that they are safe and effective to treat a particular indication. New drug applicants are not required to, and usually do not try to, show that their new drug product is better than other similar, already approved, products.

1. Requirements for submitting patent information.

69. The Act and FDA regulations require that a sponsor of an NDA submit to FDA a list of patents claiming the approved drug substance or drug product, or claiming an approved method of using the drug product described in the NDA.

70. Specifically, section 505(b)(l) of the Act requires NDA applicants to file as part of the NDA,

> the patent number and the expiration date of any patent which claims the drug for which the applicant submitted the application or which claims a method of using such drug and with respect to

[5] 21 U.S.C. §§ 301–392.

[6] 21 U.S.C. § 355(a), (b).

> which a claim of patent infringement could reasonably be asserted if a person not licensed by the owner engaged in the manufacture, use, or sale of the drug."[7]

71. Section 505(c)(2) of the Act imposes an additional patent submission requirement on holders of approved NDAs when those holders subsequently obtain new patent information that could not have been submitted with the NDA:

> If the patent information described in subsection (b) of this section could not be filed with the submission of an application under subsection (b) of this section because the application was filed before the patent information was required under subsection (b) of this section or a patent was issued after the application was approved under such subsection, the holder of an approved application shall file with the Secretary the patent number and the expiration date of any patent *which claims the drug for which the application was submitted* or *which claims a method of using such drug* and with respect to which *a claim of patent infringement could reasonably be asserted* if a person not licensed by the owner engaged in the manufacture, use, or sale of the drug.[8]

72. The statutory language did not change during the time periods relevant to this complaint.

73. When Takeda submitted patent information regarding the '584 Met Combo Patent and '404 Insulin Combo Patent for ACTOS—in 1999 and 2002, respectively—the original FDA final rule applied.

74. On October 3, of 1994, the FDA issued final rules, including new section 314.53 addressing the submission of patent information. The rule read, in part:

> **(b) Patents for which information must be submitted.** An [NDA] applicant … shall submit information on *each patent that claims the drug* or a method of using *the* drug *that is the subject of the new drug application* or amendment or supplement to it *and with*

[7] (21 U.S.C. § 355(b)(1) (emphasis added).

[8] (21 U.S.C. § 355(c)(2) (emphasis added).

> *respect to which a claim of patent infringement could reasonably be asserted if a person not licensed by the owner of the patent engaged in the manufacture, use, or sale of the drug product.* For purposes of this part, such patents consist of drug substance (ingredient) patents, drug product (formulation and composition) patents, and method of use patents. … For patents that claim a drug substance or drug product, the applicant shall submit information *only* on those patents that *claim a drug product that is the subject of a pending or approved application*, or that claim a drug substance that is a component of such a product. For patents that claim a method of use, the applicant shall submit information only on those patents that claim indications or other conditions of use of a pending or approved application.[9]

75. The rule also included general reporting requirements, including that the applicant must submit information about the type of claims contained in the patent:

> (c) Reporting requirements-
>
> (1) General requirements. An applicant described in paragraph (a) of this section shall submit the following information for each patent described in paragraph (b) of this section:
>
> (i) Patent number and the date on which the patent will expire.
>
> (ii) *Type of patent, i.e., drug, drug product, or method of use.*
>
> (iii) Name of the patent owner.
>
> (iv) If the patent owner or applicant does not reside or have a place of business within the United States, the name of an agent (representative) of the patent owner or applicant who resides or maintains a place of business within the United States authorized to receive notice of patent certification under section 505(b)(3) and (j)(2)(B) of the act and §§ 314.52 and 314.95.[10]

76. The rule also required a specific declaration for formulation, composition, and/or method of use patents:

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[9] *Abbreviated New Drug Application Regulations: Patent and Exclusivity Provisions*, 59 Fed. Reg. 50338, 50344 (Oct. 3, 1994) (new and final rule publishing text of newly created § 314.53 – Submission of patent information and responding to comments re that section) (emphasis added).

[10] *Id.* at § 314.53(c)(1).

> **(c)(2)(i) Original declaration.** For each formulation, composition, or method of use patent, … the applicant shall submit the following declaration:
>
> The undersigned declares that Patent No. _____ covers the formulation, composition, and/or method of use *of (name of drug product)*. This product is (currently approved under section 505 of the Federal Food, Drug, and Cosmetic Act) [or] (the subject of this application for which approval is being sought): _____[11]

The rule also required a signature from "the applicant or patent owner, or the applicant's or patent owner's attorney, agent (representative) or other authorized official."[12]

77. During and as part of its rule making, the FDA considered and rejected argument that the Act only required NDA applicants to provide patent numbers and patent expiration dates. The FDA rejected the argument and, in the Federal Register, explained that requiring additional patent information was consistent with the purposes of the Act, particularly in light of the FDA's lack of patent expertise:

> because section 505(b)(1) of the act specifically requires applicants to "file with the application the patent number and the expiration date of any patent which claims the drug for which the applicant submitted the application or which claims a method of using such drug," and because FDA lacks patent law expertise, the agency strongly encourages applicants to identify, to the best of their ability, the type of patent covering the drug or drug product. This information will help FDA determine which claims cover the drug or drug product and which claims cover a method of use.[13]
>
> FDA does not have the resources or the expertise to review patent information for its accuracy and relevance to an NDA. Therefore, the agency declines the comment's requests to ensure

[11] *Id.* at § 314.53(c)(2)(i).

[12] *Id.* at § 314.53(c)(4).

[13] *Abbreviated New Drug Application Regulations: Patent and Exclusivity Provisions*, 59 Fed. Reg. 50338, 50344 (Oct. 3, 1994) (new and final rule). *See also id.* ("*if* the formulation patent claimed *the drug product* in the application, the applicant must file information on that patent.").

> that patent information is complete and relevant to an NDA and to confirm, upon request, the validity of patent information submitted to the agency. The agency believes that the declaration requirements under § 314.53(c), as well as an applicant's potential liability if it submits an untrue statement of material fact, will help ensure that accurate patent information is submitted.[14]

78. The FDA likewise considered and rejected a comment suggesting that there was no need to provide information about distinct formulation, composition, and method or use claims. The FDA concluded that NDA applicants should identify which claims cover the drug or drug product and which claims cover a method of use:

> [A] comment said that a patent may contain formulation, composition, and method of use claims. The comment suggested deleting the proposed rule's classification of patents and replacing it with a general certification that the patents listed by the applicant contain claims with respect to which the applicant could reasonably assert a claim of infringement against a person engaged in the unlicensed manufacture, use, or sale of the drug for which the application was submitted.
>
> *FDA acknowledges that a patent may contain a variety of claims*, and has revised proposed § 314.53(c)(2) by creating a single certification statement. … However, because section 505(b)(1) of the act specifically requires applicants to "file with the application the patent number and the expiration date *of any patent which claims the drug for which the applicant submitted the application* or which claims a method of using such drug," and because FDA lacks patent law expertise, the agency strongly encourages applicants to identify, to the best of their ability, the type of patent covering the drug or drug product. This information will help FDA determine *which claims cover the drug or drug product and which claims cover a method of use.*[15]

79. The FDA observed that failure to properly provide patent information may negatively affect other applicants:

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[14] *Id.* at 50345.

[15] *Id.* at 50343-44 (emphasis added).

> Failure to list a patent may also result in injury to other applicants who devote resources towards submitting applications for duplicate products without realizing that those products may be covered by the patent.[16]
>
> If FDA provided for a longer time period, the Orange Book and its supplements might be less likely to contain current patent information for each product, and potential applicants might be misled by outdated patent information.[17]

80. Elsewhere in the commentary accompanying the amendment, the FDA stated:

> FDA does not have the expertise to review patent information. The agency believes that its scarce resources would be better utilized in reviewing applications rather than reviewing patent claims.[18]
>
> The requirement in § 314.53(b) and (c) that applicants provide information on the type of patent … is consistent with the purpose of section 505(b)(1) of the act.[19]
>
> The statute expressly requires applicants to file "the patent number and the expiration date of any patent which claims the drug for which the applicant submitted the application * * *" (section 505(b)(1) of the act). Thus, if the formulation patent claimed the drug product in the application, the applicant must file information on that patent.[20]

81. On June 18, 2003, the FDA amended § 314.53 "to help ensure that NDA applicants submit only appropriate patents." The amendment included a mandatory form for providing patent information after an NDA has been approved, requiring applicants to identify, among other things, whether the patent claims the approved product:

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[16] *Id.* at 50344.

[17] *Id.* at 50344.

[18] *Id.* at 50343.

[19] *Id.* at 50343.

[20] *Id.* at 50344.

3. Drug Product (Composition/Formulation)		
3.1 Does the patent claim the approved drug product as defined in 21 CFR 314.3?	☐ Yes	☐ No
3.2 Does the patent claim only an intermediate?	☐ Yes	☐ No
3.3 If the patent referenced in **3.1** is a product-by-process patent, is the product claimed in the patent novel? (An answer is required only if the patent is a product-by-process patent.)	☐ Yes	☐ No
FDA will not list the patent in the Orange Book as claiming the drug product if: • **the answer to question 3.1 is "No," or,** • **the answer to question 3.2 is "Yes," or,** • **the answer to question 3.3 is "No."**		

82. In short, for patents claiming a drug product, the NDA applicant could submit information describing the patent as a "drug product patent" only if the patent claimed the drug product that was the subject of the NDA. The patent's drug product claim could not just claim *some* drug product—it had to claim the *relevant* drug product, *i.e.*, the FDA approved drug product as to which the NDA applicant listed the patent.

83. NDA applicants were on their honor to properly identify the "Type of patent, *i.e.*, drug, drug product, or method of use."[21]

84. The Act requires that the FDA publish patent information for approved new drugs; the FDA does so in the publication *Approved Drug Products with Therapeutic Equivalence Evaluations* (commonly called the Orange Book).[22]

85. In listing patents and patent information in the Orange Book, the FDA merely performs a ministerial act.

86. The FDA relies completely on a branded drug manufacturer's truthfulness about patent validity and applicability because the FDA does not have the resources or authority to

[21] 21 C.F.R. § 314.53(c)(2)(ii) (1999) & (2002).

[22] 21 U.S. C. § 355(b)(l), (c)(2), and (j)(7); 21 CFR § 314.53(e).

verify a branded drug manufacturer's patents and patent information for accuracy or trustworthiness.

87. The FDA expressly refused (both then and now) to police the proper listing of patents and patent information, noting that it does not have the resources or the expertise to review patent information for its accuracy and relevance to an NDA, and that it believes that the declaration requirements under § 314.53(c) requiring the applicant to declare that Patent No. ____ covers the formulation, composition, and/or method of use of (name of drug product), as well as an applicant's potential liability if it submits an untrue statement of material fact, will help ensure that accurate patent information is submitted.[23]

88. Any person may dispute the accuracy of patent information listed in the Orange Book by notifying the FDA in writing (21 CFR § 314.53(f)). But in response, the FDA simply asks the brand to verify the information it provided originally and makes no changes in the Orange Book "[u]nless the [brand] withdraws or amends" the listing.

89. Again, the FDA does not attempt to verify the accuracy of the patent information brand manufacturers supply. It simply publishes that supplied information in the Orange Book.

90. The purpose of publishing this information is to provide generic companies and other drug applicants notice of which patents allegedly protect a particular drug.

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[23] *See, e.g.*, *Abbreviated New Drug Application Regulations: Patent and Exclusivity Provisions*, 59 Fed. Reg. 50338, 50343-45 (Oct. 3, 1994) ("FDA does not have the expertise to review patent information. The agency believes that its scarce resources would be better utilized in reviewing applications rather than reviewing patent claims."). *See also* FDA/CDER response to citizen petition re: Actos and Acto*plus* met, Docket No. FDA-2009-P-0411-0010 (Mar. 15, 2010), at 9 ("In keeping with our practice of relying solely on the NDA sponsor's patent declaration describing relevant patent claims in Orange Book-listed patents, FDA will rely on Takeda's patent declarations submitted to FDA.").

2. The Hatch-Waxman amendments.

91. The Hatch-Waxman Act, enacted in 1984, simplified the regulatory hurdles for prospective generic drug manufacturers by eliminating the need to file lengthy and costly NDAs.[24] A manufacturer seeking approval to sell a generic version of a brand drug may instead file an ANDA. An ANDA relies on the scientific findings of safety and effectiveness included in a branded drug manufacturer's original NDA, but must further show that the generic drug (i) contains the same active ingredient(s), dosage form, route of administration, and strength as the brand drug, and (ii) is absorbed at the same rate and to the same extent as the brand drug—that is, that the generic drug is pharmaceutically equivalent and bioequivalent (together, "therapeutically equivalent") to the brand drug. The FDA assigns an "AB" rating to generic drugs that are therapeutically equivalent to their brand-name counterparts.

92. The FDCA and Hatch-Waxman Act operate on the presumption that bioequivalent drugs containing identical amounts of the same active ingredients, having the same route of administration and dosage form, and meeting applicable standards of strength, quality, purity and identity, are therapeutically equivalent and may be substituted for one another. Bioequivalence means that the active ingredient of the proposed generic drug would be present in the blood of a patient to the same extent and for the same amount of time as its branded counterpart.[25]

93. Congress enacted the Hatch-Waxman Act to expedite the entry of legitimate (non-infringing) generic competitors, thereby reducing healthcare expenses nationwide. Congress also sought to protect pharmaceutical manufacturers' incentives to create new and

[24] *See* Drug Price Competition and Patent Term Restoration Act, Pub. L. No. 98-417, 98 Stat. 1585 (1984).

[25] 21 U.S.C. § 355(j)(8)(B).

innovative products by, among other things, permitting a brand company to file a legitimate patent infringement lawsuit against a generic before the generic actually brought its product to market.

94. The Hatch-Waxman Act achieved both goals by advancing substantially the rate of generic product launches and ushering in an era of historic high profit margins for branded drug manufacturers. In 1983, before the Hatch-Waxman Act, only 35% of the top-selling branded drugs with expired patents had generic alternatives; by 1998, nearly all did. In 1984, annual prescription drug revenue for branded and generic drugs totaled $21.6 billion, with generic drugs accounting for 18.6% of prescriptions. By 2013, total annual prescription drug revenue had soared to over $329 billion, with generic drugs accounting for 84% of prescriptions.

95. The Hatch Waxman Act authorizes the FDA to approve the marketing of a generic drug for unpatented uses, and provide a mechanism for a generic company to identify those uses so that a less-expensive generic product can come to market. As the Supreme Court has recognized, "[t]he statutory scheme, in other words, contemplates that one patented use will not foreclose marketing a generic drug for other unpatented ones."[26]

3. Requirements regarding ANDA labeling.

96. Section 505(j)(2)(A)(i) of the Act requires that an ANDA contain "information to show that the conditions of use prescribed, recommended, or suggested in the labeling proposed for the new drug have been previously approved for a [listed drug]." This language reflects Congress's intent that the generic drug be safe and effective for each "condition of use" prescribed, recommended, or suggested in the generic drug labeling. But it does not require

[26] *Caraco Pharm. Labs., Ltd. v. Novo Nordisk A/S*, 132 S. Ct. 1670, 1677 (2012).

that an ANDA be approved for each condition of use for which the reference listed drug is approved. Thus, in § 314.92(a)(l), the FDA has explicitly stated that a proposed generic drug product must have the same conditions of use as the listed drug, "except that conditions of use for which approval cannot be granted because of . . . an existing patent may be omitted" (emphasis added).

97. The Act also requires that an ANDA contain "information to show that the labeling proposed for the new [generic] drug is the same as the labeling approved for the listed drug. . . except for changes required because of differences approved under a petition filed under [section 505(j)(2)(C) of the Act] or because the new drug and the listed drug are produced or distributed by different manufacturers" (section 505(j)(2)(A)(v) of the Act). A parallel provision appears in section 505(j)(4)(G) of the Act.[27]

98. Similarly, the regulations at § 314.94(a)(8)(iv) require the following:

> Labeling (including the container label, package insert, and, if applicable, Medication Guide) proposed for the (generic) drug product must be the same as the labeling approved for the reference listed drug, except for changes required because of differences approved under a petition filed under § 314.93 [21 CFR 314.93] or because the drug product and the reference listed drug are produced or distributed by different manufacturers.

99. Section 314.94(a)(8)(iv) sets forth examples of permissible differences in labeling that may result because the generic drug product and reference listed drug are produced or distributed by different manufacturers. These differences include the following:

> [D]ifferences in expiration date, formulation, bioavailability, or pharmacokinetics, labeling revisions made to comply with current

[27] Section 505(j)(4)(G) of the Act provides that FDA must approve an ANDA unless, among other things, the "information submitted in the application is insufficient to show that the labeling proposed for the drug is the same as the labeling approved for [the reference listed drug] except for changes required because of differences approved under [an ANDA suitability petition] or because the drug and the listed drug are produced or distributed by different manufacturers."

> FDA labeling guidelines or other guidance, or *omission of an indication or other aspect of labeling protected by patent* [emphasis added] or accorded exclusivity under section 505(j)(4)(D) of the [A]ct.[28]

100. The regulations at 21 CFR 314.127(a)(7) further provide that to approve an ANDA containing proposed labeling that omits "aspects of the listed drug's labeling [because those aspects] are *protected by patent* [emphasis added]," we must find that the "differences do not render the proposed drug product less safe or effective than the listed drug for all remaining non-protected conditions of use."

101. Relevant case law affirms an ANDA applicant's ability to carve out protected labeling without violating the "same labeling" requirement. *Bristol-Myers Squibb v. Shalala*, 91 F.3d 1493, 1500 (D.C. Cir. 1996); *Sigma-Tau Pharm., Inc. v. Schwetz*, 288 F.3d 141, 148, fn. 3 (4th Cir. 2002). In *Bristol Myers Squibb v. Shalala*, F.3d 1493, 1500 (D.C. Cir. 1996), the Court ruled that "whether the label for the new generic lists every indication approved for the use of the pioneer is a matter of indifference."[29]

102. Thus, under the statute, regulations, and applicable case law, the carve-out of patent-protected labeling is generally permitted as a permissible difference due to difference in manufacturer if the omission does not render the proposed drug product less safe or effective for the conditions of use that remain in the labeling.

103. The FDA has approved generic drug products with labeling that excludes protected conditions of use from the generic drug labeling. For example, the FDA approved

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[28] We note that, due to a series of amendments to the Act, the reference in § 314.94(a)(8)(iv) to section 505(j)(4)(D) of the Act corresponds to current section 505(j)(5)(F) of the Act.

[29] Similarly, in *Sigma-Tau Pharmaceuticals, Inc. v. Schwertz*, 288 F.3d 141, 148 n.3 (4th Cir. 2002), the Fourt Circuit upheld the right of an ANGA applicant to carve out an indication protected by orphan drug exclusivity as a permissible difference due to difference in manufacturer."

generic tramadol products with labeling that excludes a protected dosing schedule. The FDA approved a generic dronabinol product whose labeling omits information relating to use of the drug to treat anorexia associated with weight loss in AIDS patients. The FDA approved a generic ribavirin capsule drug product with labeling that omits information on the use of ribavirin capsules in combination with PEG-Intron. The FDA approved generic captopril with labeling that excluded two protected indications with corresponding protected, indication-specific dosing information. And the FDA approved generic versions of ifosamide, which had previously only been marketed by the innovator co-packaged with mesna.

104. In an April 6, 2004 response to a petition, the FDA reaffirmed its authority to approve generic ribavirin drug product with labeling that omits protected usage. The FDA reiterated its position in a March 13, 2008 response to a petition concerning ANDAs for amfostine with the protected indication carved out. In April 2008, the FDA, again, reaffirmed its authority to approve generic drug products with carve-out labeling, and denied a request that ANDAs for generic versions of Marinol be required to approve the AIDs indication. The FDA again reiterated its position in multiple other citizen petition responses, including its November 18, 2008 response addressing Pulmicort Respules and its December 4, 2008 response addressing repaglinide.

105. On June 18, 2008, the FDA confirmed that

> an ANDA's 180-day exclusivity period would not preclude approval of a subsequent ANDA referencing the same listed drug if the subsequent ANDA contains a section viii statement with respect to the patent upon which 180-day exclusivity was based and omits from the labeling information related to the use protected by the patent.

106. The very nature of the legal framework contemplates that an ANDA applicant can limit the intended use of its product to one or more uses, thereby promoting generic drug competition for the remaining, non-protected condition of use.

107. In its response to a petition addressing generic ribavirin capsules, the FDA noted that permitting generic applicants to carve out protected indications is consistent with the underlying goals of Hatch-Waxman:

> [T]he agency's interpretation – that FDA may approve an ANDA for a ribavirin capsule drug product with labeling that omits information on the use of ribavirin in combination with PEG-Intron --allows the innovator and associated patent holders to enjoy the benefits associated with their research in developing a new condition of use (*i.e.*, the use of ribavirin capsules in combination with PEG-Intron). At the same time, the agency's conclusion promotes generic competition for the remaining, non-protected condition of use for which the listed drug is approved (*i.e.*, the adult use of ribavirin capsules in combination with Intron A). Accordingly, only the agency's interpretation strikes the balance contemplated by the Hatch-Waxman Amendments.

4. ANDA patent certifications.

108. A drug product with an effective approval under section 505(c) of the Act is known as a *listed drug*. Under provisions added to the Act by the 1984 Drug Price Competition and Patent Term Restoration Act (Hatch-Waxman Amendments), Public Law No. 98-417, 98 Stat. 1585, the Act permits submission of ANDAs for approval of generic versions of listed drugs (see section 505(j) of the Act). The ANDA process shortens the time and effort needed for approval by, among other things, allowing an ANDA applicant to rely on FDA's previous finding of safety and effectiveness for a listed drug rather than requiring the ANDA applicant to independently demonstrate the safety and effectiveness of its proposed drug. To rely on such a finding, the ANDA applicant must show that its proposed drug product is the same as the listed drug in many respects (including active ingredient, dosage form, strength, route of

administration, and, with certain narrow exceptions, labeling), and that its product is bioequivalent to the listed drug.

109. Each ANDA applicant must identify the listed drug on which it seeks to rely for approval. The timing of ANDA approval depends on, among other things, the intellectual property protections for the listed drug the ANDA references and whether the ANDA applicant challenges those protections (*see* sections 505(b), (c), (j)(2)(A)(vii), and (j)(5)(B) of the Act).[30] In general, an ANDA may not obtain final approval until listed patents and marketing exclusivity have expired or until NDA holders and patent owners have had the opportunity to defend relevant patent rights in court.

110. Specifically, with respect to each patent submitted by the sponsor for the listed drug and listed in the Orange Book, the ANDA applicant generally must submit to FDA one of four specified certifications under section 505(j)(2)(A)(vii) of the Act. The certification must state one of the following:

(I) That the required patent information relating to such patent has not been filed (paragraph I certification)

(II) That such patent has expired (paragraph II certification)

(III) That the patent will expire on a particular date (paragraph III certification)

(IV) That such patent is invalid or will not be infringed by the drug for which approval is being sought (paragraph IV certification).

111. The purpose of these certifications is "to give notice, if necessary, to the patent holder so that any legal disputes regarding the scope of the patent and the possibility of

[30] Relevant intellectual property protections affecting the timing of ANDA approval include marketing exclusivity and listed patent protection for the listed drug. Marketing exclusivity is not at issue here.

infringement can be resolved as quickly as possible." *Torpharm, Inc. v. Thompson*, 260 F. Supp. 2d 69, 71 (D.D.C. 2003).

112. If an applicant files a paragraph I or II certification, the patent in question will not delay ANDA approval. If an applicant files a paragraph III certification, the applicant agrees to wait until the relevant patent has expired before seeking full effective approval of its ANDA.

113. If the patent has not expired, and the generic company is not willing to wait to launch until after expiry, there are three paths to approval: (1) a section viii statement, (2) paragraph IV certification, or (3) some combination of the two. We address these in turn. But at bottom is this: Under the procedures established in the Hatch-Waxman Amendments, an ANDA will not be approved until all listed patents: (l) have expired; (2) have been successfully challenged (3) have been subject to a paragraph IV certification pursuant to which the patent owner or NDA holder has declined to sue within 45 days; (4) have been subject to a paragraph IV certification that led to a lawsuit and either (i) a decision favorable to the ANDA applicant was reached or (ii) the automatic 30-month stay that issued upon the filing of suit has since expired; or (5) are subject to a section viii statement and a corresponding labeling carve-out.

a. Section viii method-of-use carve-outs.

114. The Hatch Waxman Act encourages generic competition for non-infringing uses. The Act recognizes that a generic may infringe one (patented) method of use without infringing another, and encourages generics to carve out would-be infringing uses in order to bring products to market quickly.

115. An ANDA applicant may submit a section viii statement asserting that the generic manufacturer will market the drug for one or more methods of use not covered by the

brand's patents (see section 505(j)(2)(A)(viii) of the Act). Section 505(j)(2)(A)(viii) of the Act provides that:

> if with respect to the listed drug referred to in [section 505(j)(2)(A)(i)] information was filed under subsection (b) or (c) for a method of use patent which does not claim a use for which the applicant is seeking approval under this subsection, [the ANDA must contain] a statement that the method of use patent does not claim such a use.

116. If an ANDA applicant files a section viii statement, the patent claiming the protected method of use will not serve as a barrier to ANDA approval.[31]

117. A section viii statement is commonly used when the brand's patent on the drug compound has expired and the brand holds patents on only some approved methods of using the drug. The ANDA applicant then proposes labeling for the generic drug that "carves out" from the brand's approved label the still-patented methods of use. *See* 21 CFR § 314.94(a)(8)(iv). The FDA may then approve the modified label under § 314.127(a)(7).[32]

118. FDA implementing regulations at 21 CFR § 314.94(a)(12)(iii) describe the applicability of the section viii statement, and states:

> If patent information is submitted under section 505(b) or (c) of the [A]ct and § 314.53 for a patent claiming a method of using the listed drug, and the labeling for the drug product for which the applicant is seeking approval does not include any indications that are covered by the use patent, [the ANDA applicant must

[31] *See also* H.R. Rep. No. 857 (Part I), 98th Cong., 2d sess. 21:

> The [ANDA] applicant need not seek approval for all of the indications for which the listed drug has been approved. For example, if the listed drug has been approved for hypertension and angina pectoris, and if the indication for hypertension is protected by patent, then the applicant could seek approval for only the angina pectoris indication.

[32] *See Caraco Pharm. Labs., Ltd. v. Novo Nordisk A/S*, 132 S. Ct. 1670, 1677 (2012) (citing 21 CFR 314.94(a)(8)(iv)).

> submit] a statement explaining that the method of use patent does not claim any of the proposed indications.[33]

119. FDA regulations also expressly recognize that by submitting a section viii statement, an ANDA applicant may omit from the proposed labeling a method of use protected by a listed patent, and therefore need not seek approval for that use.[34]

120. The right to file a section viii statement and carve out from labeling method-of-use information protected by a patent has been upheld by the courts in *Caraco Pharm. Labs., Ltd. v. Novo Nordisk A/S*, 132 S. Ct. 1670, 1677 (2012), *Purepac Pharmaceutical Company v. Thompson*, 354 F.3d 877, 880 (D.C. Cir. 2004), and *TorPharm, Inc. v. Thompson*, 260 F. Supp. 2d

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[33] The FDA has clarified that:

> [R]egulations implementing this statutory provision use the term *indications* to refer to information an ANDA applicant omits from its labeling in the context of submitting a statement that a protected use of a drug is not claimed in a listed patent (§ 314.94(a)(12)(iii)). However, the preambles for the proposed rule and final rule on patent and exclusivity provisions related to ANDA approval express no intent to distinguish between method of use and indication, using the terms interchangeably (see, e.g., 59 FR 50338 at 50347 (October 3, 1994)). Moreover, the preamble to the final rule emphasizes that an ANDA applicant does not have the option of choosing between a paragraph IV certification and a section viii statement where the patent claims only a method of use; where the labeling does not include the indication, only the section viii statement is appropriate (id.). The preamble to the proposed rule states that where "the labeling for the applicant's proposed drug product does not include any indications that are covered by the use patent," the ANDA applicant would submit a section viii statement rather than a paragraph iv certification (54 FR 28872 at 28886 (July 10, 1989)).

FDA/CDER response to citizen petitions re: Prandin, Docket Nos. FDA-2008-P-0343-0009 and 2008-P-0411-0006 (Dec. 4, 2008), at 6 n.6.

[34] *See also* the final rule, Applications for FDA Approval to Market a New Drug: Patent Submission and Listing Requirements and Application of 30-Month Stays on Approval of Abbreviated New Drug Applications Certifying That a Patent Claiming a Drug Is Invalid or Will Not Be Infringed (68 FR 36676 (June 18, 2003)). In the preamble to this final rule, FDA stated that the section viii statement permits an ANDA applicant to "avoid certifying to a patent by stating that it is not seeking approval for the use claimed in the listed patent" (68 FR 36676 at 36682). FDA stated, "[o]ur position has been that, for an ANDA applicant to file a Section viii statement, it must 'carve-out' from the proposed ANDA labeling, the labeling protected by the listed patent" (id.).

69, 73 (D.D.C. 2003), *aff'd sub nom. Purepac Pharm. Co. v. Thompson*, 354 F.3d 877 (D.C. Cir. 2004).

121. Exploitation of the Hatch-Waxman statutory scheme by brand drug manufacturers to forestall the generic market became apparent in the 1990's.

122. In July 2002, the Federal Trade Commission (FTC) published a study that reported on the growing industry trend for brand manufacturers to prevent or delay the marketing of generic drugs by submitting inaccurate or improper patent information to the FDA for listing in the Orange Book.[35]

123. The FTC report cited one case wherein a brand company facing patent expiration listed a new patent with the FDA in order to extend its right over the drug. Relying on the brand company's representation and unaware that the new patent listing, in fact, covered neither the drug's compound nor any method of using it, the FDA declined to approve the generic drug. In response, the generic ANDA applicant sued to remove the improper Orange Book patent listing, but the Federal Circuit found that it had no such right of action under Hatch Waxman. Thus, the generic manufacturer's only option was to file a paragraph IV certification of noninfringement that immediately triggered the infringement suit and forced the generic to wait out the statutorily prescribed 30-month stay of ANDA approval by the FDA.[36]

124. To address these anticompetitive abuses, Congress authorized generic manufacturers in patent infringement suits to assert a legal counterclaim challenging the brand

[35] *See* FTC, Generic Drug Entry Prior to Patent Expiration: An FTC Study, pp. iii-vi (July 2002).

[36] *Mylan Pharmaceuticals, Inc. v. Thompson*, 268 F.3d 1323 (C.A.Fed.2001).

manufacturer's submission of patent information to the FDA.[37] The applicable provision states that a generic ANDA applicant sued for patent infringement may:

> assert a counterclaim seeking an order requiring the [brand] to correct or delete the patent information submitted by the [brand] under subsection (b) or (c) [of § 355] on the ground that the patent does not claim either—
>
> (aa) the drug for which the [brand's NDA] was approved; or
>
> (bb) an approved method of using the drug.[38]

125. This statutory amendment provides recourse to the generic manufacturer that may now seek a court order for the correction or deletion of improper patent information that is blocking FDA approval of the generic ANDA product.

b. Paragraph IV litigation and 30-month stays.

126. A generic manufacturer's second option for getting approval before all Orange Book listed patents have expired is to file a paragraph IV certification stating that a listed patent "is invalid or will not be infringed by the manufacturer, use, or sale of the [generic] drug" (section 505(j)(2)(A)(vii)(VI)). A generic manufacturer will typically take this path in either of two situations: if it wants to market the drug for all uses (rather than carving out those still allegedly under patent) or if it discovers that a carve-out label is not an option (if, for example, the product is only approved for a single method of use).

127. The applicant filing a paragraph IV certification must also provide notice to the NDA holder and the patent owner stating that he has submitted an ANDA with a paragraph IV certification and explaining the factual and legal bases for the applicant's opinion that the patent is invalid or not infringed (see section 505(b)(2)(B) and (j)(2)(B) of the Act).

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[37] *See* Medicare Prescription Drug, Improvement, and Modernization Act of 2003, 117 Stat. 2452.

[38] 21 U.S.C. § 355(j)(5)(c)(ii)(1).

128. Filing a paragraph IV certification provokes litigation. The patent statute treats such filing as an act of technical infringement and provides the brand company an opportunity to sue. *See* 35 U.S.C. § 271(e)(2)(A). If the patent owner or NDA holder brings a patent infringement suit against the ANDA applicant within 45 days of the date it received notice of the paragraph IV certification, the approval of the ANDA will automatically be stayed for 30 months from the date of such receipt by the patent owner and NDA holder, unless a court decision is reached earlier in the patent case or the patent court otherwise orders a longer or shorter period (see section 505(c)(3)(C) and (j)(5)(B)(iii) of the Act). When the 30 months have expired, the patent ceases to be a barrier to final FDA ANDA approval, even if the patent litigation is ongoing. Similarly, if the NDA holder and patent owner receive notice of a paragraph IV certification and decline to sue within 45 days of receipt of notice, the patent will not be a barrier to final ANDA approval.

129. If a generic drug manufacturer files a paragraph IV certification, a branded drug manufacturer can delay FDA approval of the ANDA simply by suing the ANDA applicant for patent infringement. If the branded drug manufacturer initiates a patent infringement action against the generic drug manufacturer filer within forty-five days of receiving notification of the paragraph IV certification ("Paragraph IV Litigation"), the FDA will not grant final approval to the ANDA until the earlier of (a) the passage of 30 months, or (b) the issuance of a decision by a court that the patent is invalid or not infringed by the generic drug manufacturer's ANDA. Until one of those conditions occurs, the FDA may grant "tentative approval" but cannot grant "final approval" which would authorize the generic drug manufacturer to market its product. The FDA may grant an ANDA tentative approval when it determines that the ANDA would otherwise be ready for final approval but for the 30-month stay.

130. An ANDA may only receive tentative approval if it "meets the requirements of [21 U.S.C. § 355(j)(2)(A)], but cannot meet the requirements of this subparagraph, there is a period of exclusivity for the listed drug under subparagraph (F) or section 355a of this title, or there is a 7-year period of exclusivity for the listed drug under section 360cc of this title."[39] So before any ANDA receives tentative approval, the FDA must have determined that the ANDA satisfied all the requirements of section (j)(2)(A).

131. Section (j)(2)(A) requires every ANDA to contain:

> (i) information to show that the conditions of use prescribed, recommended, or suggested by the labeling proposed for the new drug have been previously approved for [the RLD];
>
> * * *
>
> (v) information to show that the labeling proposed for the new drug is the same as the labeling approved for the [RLD] except for changes required because of differences approved under a petition filed under subparagraph (C) or because the new drug and the [RLD] are produced or distributed by different manufacturers.
>
> * * *
>
> (viii) if with respect to the [RLD] information was filed under subsection (b) or (c) of this section for a method of use patent which does not claim a use for which the applicant is seeking approval under this subsection, a statement that the method of use patent does not claim such a use.[40]

132. FDA regulations require an ANDA to include a side-by-side comparison of the label from the RLD and the ANDA product, which must be "the same" except for differences

[39] 21 U.S.C. § 355(j)(5)(B)(iv)(II)(dd). *See also Ranbaxy Labs, Ltd. v. Burwell*, 82 F. Supp.3d 159, 167-68 (D.D.C. 2015) (tentative approval means the applicant has met the requirements of paragraph (2)(A)).

[40] 21 U.S.C. § 355(j)(2)(A)(i), (v), and (viii). Unlike a paragraph III or paragraph IV certification, the filing of a section (viii) statement will not by itself delay approval of an ANDA. *AstraZeneca LP v. Apotex, Inc.*, 633 F.3d 1042, 1046 (Fed. Cir. 2010).

resulting from, *inter alia*, "omission of an indication or other aspect of labeling protected by patent or accorded exclusivity under section 505(j)(5)(F) of the act."[41] As to patent certifications, the regulations provide that "for a patent claiming a method of using the [RLD], [if] the labeling for the drug product for which the applicant is seeking approval does not include any indications what are covered by the use patent, a statement explaining that the method of use patent does not claim any of the proposed indications."[42]

133. The regulations also provide that the FDA "will refuse to approve" any ANDA as to which

> [i]nformation submitted in the [ANDA] is insufficient to show that the labeling proposed for the drug is the same as the labeling approved for the [RLD] … except … because aspects of the [RLD's] labeling are protected by patent, or by exclusivity, and such differences do not render the proposed drug product less safe or effective than the listed drug for all remaining, nonprotected conditions of use.[43]

134. In *MylanPharms., Inc. v. Sebelius*, the court described tentative approval as being granted "when all scientific and procedural conditions have been met, but final approval is blocked by the 30-month stay, marketing exclusivity, or some other barrier arising from patent infringement litigation."[44]

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[41] 21 C.F.R. § 314.94 (a)(8)(iv)

[42] 21 C.F.R. § 314.94(a)(12)(iii).

[43] 21 C.F.R. § 314.127(a)(7).

[44] 856 F. Supp.2d 196, 201 n.3 (D.D.C. 2012) (citing 21 U.S.C. § 355(j)(5)(B)(iv)(II)(dd)(AA)). The court also pointed out that "tentative approval" does not mean "final approval" and that no drug can be legally marketed until it receives the latter. *Id.*; *see also Ranbaxy Labs. Ltd. v. FDA*, 307 F. Supp.2d 15, 19-21 (D.D.C. 2004) ("Approvals do not become effective by operation of law because the FDA has an ongoing health and safety responsibility to perform."); 21 U.S.C. § 355(j)(5)(B)(iv)(II)(dd)(BB) ("A drug that is granted tentative approval by the Secretary is not an approved drug and shall not have an effective approval until the Secretary issues an approval after any necessary additional review of the application."); 21 C.F.R. § 314.107(b)(3)(v) ("Tentative approval of an application does not constitute 'approval' under FDCA "and cannot, absent a final approval letter from the agency, result in an effective approval")..

135. As an incentive to generic drug manufacturers to seek approval of generic alternatives to branded drugs, the first generic drug manufacturer to file an ANDA containing a paragraph IV certification typically receives a period of protection from competition from other generic versions of the drug. For paragraph IV certifications made before December 8, 2003, the first generic drug manufacturer applicants received 180 days of market exclusivity, which could not be forfeited and was triggered only by commercial marketing of the generic product. In other words, secondary ANDA filers were required to wait until the first-filer both (i) launched its generic product, and (ii) enjoyed its 180 days of market exclusivity. For paragraph IV certifications made after December 8, 2003, the first generic drug manufacturer applicant receives 180 days of market exclusivity (unless some forfeiture event, like that discussed below, occurs). This means the first approved generic drug will be the only available ANDA-based generic drug for at least six months following generic entry.

136. Branded drug manufacturers can "game the system" by describing patents as containing relevant drug product claims (even if the patents, in fact, do not do so) and suing any generic drug manufacturer competitor filing an ANDA with a paragraph IV certification (even if the competitor's product does not actually infringe the listed patents) in order to delay final FDA approval of an ANDA for up to 30 months. That branded drug manufacturers often sue generic drug manufacturers under Hatch-Waxman simply to delay generic drug competition—as opposed to enforcing a valid patent that is actually infringed by the generic drug—is demonstrated by the fact that in 73% of the paragraph IV Litigation cases studied generic drug manufacturers prevailed, either by obtaining a judgment of invalidity or non-infringement or by the patent holder's voluntary dismissal of the suit.

137. For paragraph IV certifications made before December 8, 2003, the first ANDA applicant could help a branded drug manufacturer "game the system" through creation of a

regulatory bottleneck. Because secondary generic ANDA applicants had to wait until the expiration of the first-filer's 180-day exclusivity period, and that 180-day exclusivity period did not start to run until the first-filer actually launched its generic product, first-filers could be induced by brand manufacturers to delay their generic product launch, which, in turn, delayed the 180-day exclusivity triggering event that needed to pass before all other secondary generic filers could enter the market.

138. On December 8, 2003, Congress enacted the Medicare Prescription Drug Improvement and Modernization Act of 2003 ("MMA") to make it more difficult for branded drug and generic drug manufacturers to conspire to delay the start of the first-filer's 180-day period of generic market exclusivity. The MMA outlines a number of conditions under which an ANDA applicant forfeits its eligibility for 180-day exclusivity, making way for other ANDA filers to launch their generic drug products. For example, forfeiture occurs if the first ANDA applicant fails to obtain tentative approval within 30 months from filing, unless the failure is caused by a change in, or review of, the approval requirements.

139. Under the "failure to market" provision, a first ANDA applicant forfeits 180-day exclusivity if it fails to market its generic drug by the later of: (a) the earlier of the date that is (i) 75 days after receiving final FDA approval; or (ii) 30 months after the date it submitted its ANDA; or (b) the date that is 75 days after the date as of which, as to each of the patents qualifying the first applicant for exclusivity (*i.e.*, as to each patent for which the first applicant submitted a paragraph IV certification), at least one of the following has occurred: (i) a final decision of invalidity or non-infringement; (ii) a settlement order entering final judgment including a finding the patent is invalid or not infringed; or (iii) the NDA holder delists the patent from the FDA Orange Book.

140. Branded drug manufacturers and first-filing generic drug manufacturers can structure their settlements in order to intentionally skirt the MMA's failure-to-market provisions and keep the 180-day exclusivity bottleneck in place. For example, they can settle their litigation before a final judgment of invalidity or non-infringement can be entered with respect to each of the patents for which the first applicant submitted a paragraph IV certification, or seek a consent judgment that does not include a finding that all of the patents for which the first applicant submitted a paragraph IV certification were invalid or not infringed. When that happens, in order to trigger forfeiture and gain access to the market, subsequent ANDA applicants are forced to obtain a judgment that all patents for which the first filing generic drug manufacturer filed paragraph IV certifications are invalid or not infringed. This may require the subsequent ANDA applicant to initiate a declaratory judgment action concerning patents that the branded drug manufacturer did not assert against it in a Paragraph IV Litigation.

141. Branded drug manufacturers and their would-be generic competitors can also use license agreements as part of a scheme to cloak their anti-competitive settlements under the guise of purportedly pro-competitive actions.

142. Courts recognize that licensing practices can have significant anticompetitive effects, and that licensing practices can serve as a mask for collusive conduct between the parties. This is particularly so where restrictions in the license primarily favor the licensee (here, the generic company) rather than the licensor (here, the branded drug company).

143. The Supreme Court has held that patent licensing agreements can violate the federal antitrust laws, even when the license is limited to granting rights within the "scope of the patent." The reach of the Sherman Act, which prohibits all agreements to fix prices, is

broad enough to reach agreements between parties that purport to stay within an otherwise lawful patent monopoly, yet result in anticompetitive harm outside that monopoly.

144. A patentee is not immune from antitrust scrutiny for payments made to a would-be competitor to get that competitor to forgo any challenge to its patent. If two parties agree to refrain from competing that agreement is subject to antitrust scrutiny regardless of its form, even if such form might be wholly lawful in another context (*e.g.*, a settlement or license agreement).

c. Split section viii and paragraph IV certifications.

145. The FDA's practice is to allow a "split certification" with both a paragraph IV certification and a section viii patent when a listed patent claims both the drug (or an aspect of the drug, such as its formulation) and a method of using the drug. When the patent contains multiple claims, an ANDA applicant may file a paragraph IV certification to some claims and a section viii statement as to others.

146. The FDA's position is that a paragraph IV certification and a section viii statement "are not overlapping, and an applicant does not have the option of making a certification under 314.94(a)(12) in lieu of, or in additional to, a statement under 314.94(a)(12)(iii)."[45] The FDA further notes:

> If, however, there are listed patents that present both a product and method of use claim, the applicant may file a paragraph IV certification with respect to the product patent or patent claim and a statement that the product *that is the subject of the application*, does not involve a patented method of use with respect to method of use patent or patent claim.[46]

[45] *See* final rule, Abbreviated New Drug Application Regulations; Patent and Exclusivity Provisions (59 FR 50338 at 50347 (October 4, 1994)).

[46] *Id.* (emphasis added).

147. A combination patent with multiple claims can be evaluated claim by claim, with a paragraph IV certification being applicable to some claims and a section viii statement being applicable to other claims.

148. The correct approach to address a combination patent is to submit a paragraph IV certification to claims covering the drug that is the subject of the application and a section viii statement for the claims covering the method of use for the drug that the generic intends to carve out from the label. The FDA has a consistent practice of permitting ANDA applicants to submit applications containing both a paragraph IV certification and a section viii statement for the same patent.[47]

149. FDA regulations implementing 314.94(a)(12)(iii) use the term "indications" to refer to information an ANDA applicant omits from its labeling in the context of submitting a statement that a protected use of a drug is not claimed in a listed patent.[48] But the preambles for the proposed rule and final rule on patent and exclusivity provisions related to ANDA approval express no intent to distinguish between method of use and indication, using the terms interchangeably.[49]

150. The preamble to the final rule also emphasizes that an ANDA applicant does not have the option of choosing between a paragraph IV certification and a section viii statement where the patent claims only a method of use. Where the labeling does not include the

[47] *See, e.g.*, FDA/CDER response to citizen petitions re: Prandin, Docket Nos. FDA-2008-P-0343-0009 and 2008-P-0411-0006 (Dec. 4, 2008); FDA/CDER response to citizen petition re: Naropin, Docket No. FDA-2009-P-0601-0006 (Jun. 17, 2010); Dear Applicant Letter from FDA/CDER re: Precedex, Docket No. FDA-2014-N-0087-0025.

[48] 314.94(a)(12)(iii).

[49] *See, e.g.*, 59 FR 50339 at 50346 (Oct. 3, 1994).

indication, only the section viii statement is appropriate.[50] The preamble to the proposed rule states that where "the labeling for the applicant's proposed drug product does not include any indications that are covered by the use patent, the ANDA applicant would submit a section viii statement rather than a paragraph iv certification.[51]

5. Consequences of providing incorrect or misleading patent information.

151. Important regulatory and competitive consequences flow from the distinction between patents described as containing relevant drug product claims, and patents described as containing only method-of-use claims.

152. As the Supreme Court recognized,

> [The Hatch Waxman] Amendments instruct the FDA (assuming other requirements are met) to approve an ANDA filed with a section viii statement when it proposed to market a drug for only unpatented method of use. To fulfill that charge, the FDA must determine whether any patent covers a particular method of use; and to do that, the agency (which views itself as lacking expertise in patent matters …) relies on the [patent information] submitted in the regulatory process. [Inaccurate patent information] therefore throws a wrench into the FDA's ability to approve generic drugs as the statute contemplates.[52]

153. If the patentee describes the patent in the patent information as containing a relevant drug product claim, an ANDA applicant desiring to market its generic product before the patent expires must file a paragraph IV certification, certifying that the patent is invalid,

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[50] 59 FR 50338 at 50246 (Oct. 3, 1994).

[51] 54 FR 28872 at 2886 (July 10, 1989).

[52] *Caraco Pharm. Labs., Ltd. v. Novo Nordisk A/S*, 132 S. Ct. 1670, 1684, 182 L. Ed. 2d 678 (2012) (internal citation omitted); *see also id.* at 1688 (recognizing the FDA's "statutory duty to approve generic drugs that do not infringe patent rights"). *Caraco* involved use codes, a specific type of patent information that must be provided under the Act.

unenforceable, or would not be infringed by the generic product.[53] The patentee and/or NDA holder then has the opportunity to obtain an automatic 30-month stay on generic competition by filing a patent infringement lawsuit against the ANDA applicant. In addition, and of particular importance here, the FDA is prohibited from approving a subsequent applicant's ANDA until 180 days after the first-filer has entered the market.[54] This 180-day exclusivity creates a "bottleneck" that delays *all* generic competition until 180 days after the first-filer enters the market.

154. By contrast, if the patentee describes the patent as containing only relevant method-of-use claims, an ANDA applicant can submit a section viii statement.[55] If an ANDA applicant makes only a section viii statement, then the patentee or NDA holder *cannot* obtain an automatic 30-month stay on generic competition even if it sues the ANDA applicant for patent infringement. And the FDA can approve an ANDA containing only a section viii statement *without regard* to whether any other ANDA applicant is otherwise entitled to a 180-day exclusivity period.

155. As the FDA has repeatedly articulated, when a patent holder identifies a patent as claim both a drug product and a method of use, and an ANDA applicant chooses to submit a section viii statement with respect to any method-of-use claims, the ANDA applicant must also

[53] 21 U.S.C. § 355(j)(2)(A)(vii)(IV); 21 C.F.R. § 314.94(a)(12)(i)(A)(4).

[54] 21 U.S.C. § 355(j)(5)(B)(iv).

[55] 21 U.S.C. § 355(j)(2)(A)(viii); 21 C.F.R. § 314.94(a)(12)(iii).

submit a paragraph I, II, III, or IV certification for any product claims.[56] And, again, the only way to get approval before the patent expires is to submit a paragraph IV certification.

156. Whether a patent actually claims the relevant drug product is irrelevant for purposes of paragraph IV certifications. Rather, FDA regulations and instructions made unmistakably clear that the *patent information* submitted by the NDA applicant determined whether generic manufacturers would be permitted to make paragraph IV certifications and thus would be eligible for the 180-day exclusivity period.[57]

157. In short, describing a patent as containing a relevant drug product claim gives the patentee two key competitive advantages—an automatic 30-month stay on generic competition, and a bottleneck that delays all generic competition until 180 days after the first generic filer enters the market.

V. FACTS

A. The '777 ACTOS Compound Patent issues and ACTOS launches.

158. On August 18, 1987, the United States Patent and Trade Office (the "PTO") issued to inventors Kanji Meguro and Takeshi Fujita U.S. Patent No. 4,687,777 (the "'777 ACTOS Compound Patent") entitled "Thiazolidinedione Derivatives, Useful As Antidiabetic Agents." The patent was at first assigned to Takeda Chemical Industries, Ltd., and then later

[56] *See, e.g.*, FDA/CDER response to citizen petitions re: Prandin, Docket Nos. FDA-2008-P-0343-0009 and 2008-P-0411-0006 (Dec. 4, 2008); FDA/CDER response to citizen petition re: Actos and Acto*plus* met, Docket No. FDA-2009-P-0411-0010 (Mar. 15, 2010).

[57] *See, e.g.*, FDA Proposed Rule, *Abbreviated New Drug Application Regulations*, 54 FR 28872, at 28885 (July 10, 1989) ("the patent information submitted to FDA, whether or not published in the list, should be the basis of the [generic company's] certification"); 21 C.F.R. § 314.94(a)(12)(iii) (ability to submit only a section viii statement is based on "patent information … submitted under … § 319.53"). As the Supreme Court recognized, "'Patent information submitted … under subsection (b) or (c)' most naturally refers to patent information provided as part of the comprehensive scheme of regulation premised on those subsections;" "the word 'under' naturally reaches beyond that most barebones information to other patent materials the FDA demands in the regulatory process." *Caraco Pharm. Labs., Ltd. v. Novo Nordisk A/S*, 132 S. Ct. 1670, 1684, 182 L. Ed. 2d 678 (2012) (internal citation and quotation omitted).

to another Takeda entity. The '777 ACTOS Compound Patent purports to claim the novel compound commonly known under the nonproprietary name "pioglitazone" and its pharmacologically acceptable salts including pioglitazone hydrochloride, the active ingredient for ACTOS. Because both ACTOS and ACTO*plus* met use the same active pharmaceutical ingredient, pioglitazone, each of those products are covered by the '777 ACTOS Compound Patent. After accounting for applicable extensions, the '777 patent was set to expire on January 17, 2011.

159. On January 15, 1999, Takeda submitted NDA 021073 to the FDA, seeking approval to manufacture, market, and sell ACTOS.

160. On July 15, 1999, the FDA approved Takeda's NDA for the use of ACTOS to improve glycemic control in adults with Type 2 diabetes – either as monotherapy or in combination with a sulfonylurea, metformin, or insulin.

161. As permitted by the FDCA and applicable regulations, Takeda submitted the '777 ACTOS Compound Patent for listing in the Orange Book as a drug substance patent covering ACTOS.

162. Following the FDA's July 15, 1999 approval, Takeda began marketing ACTOS in the U.S. market.

163. At the time of the launch, the FDA had determined, at Takeda's request, that the ACTOS NDA had a new chemical entity ("NCE"). As such, Takeda was entitled to NCE exclusivity, preventing submission of an ANDA until expiration of five years from NDA approval (which, for ACTOS, meant the NCE exclusivity expired on July 15, 2004). But, if an ANDA applicant certified that one or more of the patents listed for the reference listed drug

("RLD") is invalid or not infringed (*i.e.*, files a paragraph IV certification to the patent), then the ANDA may be submitted one year earlier (*i.e.*, for ACTOS, July 15, 2003).[58]

164. In short, when ACTOS was approved in July of 1999, Takeda knew (i) that it had NCE exclusivity such that the first ANDAs (if based on paragraph IV certifications) would not be filed until the earliest of July15, 2003, (ii) that it had ostensible compound patent coverage for the active pharmaceutical ingredient pioglitazone until January 17, 2011, but (iii) that when efforts to gain generic entry would begin as early as July 15, 2003, it would have no legitimate, practical basis to exclude competition for the ACTOS product itself beyond January 17, 2011. It also knew that successful entry of generics, whether before or after the '777 ACTOS Compound Patent expired, would likely mean the near complete loss of sales from the ACTOS product.

B. The '584 Met Combo Patent and the '404 Insulin Combo Patent are issued, and Takeda wrongfully identifies them to the FDA as compound patents covering ACTOS.

165. During the 1990s and as a means of extending ACTOS' market exclusivity, Takeda employees explored ways to argue they had developed products that were to be used in combination with pioglitazone even though the label for ACTOS itself already disclosed that "as monotherapy and in combination with sulfonylurea, metformin, or insulin, ACTOS improved glycemic control in both males and females."

166. On October 12, 1999, the PTO issued United States Patent No. 5,965,584 (the "'584 Met Combo Patent") entitled "Pharmaceutical Composition." The patent was assigned to Takeda Chemical Industries, Ltd. and later to a different Takeda entity. The '584 Met Combo Patent purports to claim a pharmaceutical composition comprising pioglitazone or salts thereof

[58] *See* 21 U.S.C. § 355(j)(5)(F)(ii).

in combination with a biguanide (*e.g.*, metformin) and methods for treating diabetes which comprise administering a therapeutically effective amount of pioglitazone or salts thereof *in combination with a biguanide* (*e.g.*, metformin). The '584 patent expires on June 19, 2016.

167. The '584 Met Combo Patent does *not* claim the compound pioglitazone (the active ACTOS drug ingredient); at most, the '584 Combo Patent claims a method of using pioglitazone in combination with another active ingredient, metformin. As a result, the '584 patent does not conceivably cover the standalone pioglitazone drug product, and thus would not cover the drug product ACTOS. As to ACTOS, the '584 Met Combo Patent was at most only a method-of-use patent, and not a drug product or composition patent.[59]

168. As such, a lawfully accurate listing in the Orange Book would be to list the '584 Met Combo Patent as only a method-of-use patent under the ACTOS NDA listed drug status. In doing so, any ANDA applicant could take advantage of the section viii statement path contemplated by Hatch Waxman to encourage the introduction of non-infringing uses of a drug. Here, that would mean that upon the expiration (at the end of January 2011) of the drug product patent for ACTOS (the '777 ACTOS Compound Patent), generics could obtain final FDA approval for generic ACTOS even though patents still covered the combination of ACTOS with metformin (because that generic would carve-out of its label the use of pioglitazone *in combination with a biguanide*). In this way, the metformin combination method-of-use claims for ACTOS in the '584 patent would not stand in the way of the introduction of generic ACTOS for non-combination metformin use.

[59] The '584 Met Combo Patent only potentially covers a combination product using both those ingredients. As such, the '584 Met Combo Patent arguably covers as a product what eventually would be sold by Takeda as ACTO*plus* met, the purported commercial embodiment of the '584 Met Combo Patent.

169. Takeda knew this. But rather than file lawfully accurate information with the FDA for Orange Book listing purposes, it misrepresented the scope of the '584 Met Combo Patent. Takeda's original and later patent information submissions were shams infected by fraud and done with anticompetitive intent.

170. On or about November 5, 1999 – and despite knowing its newly acquired '584 Met Combo Patent in no legitimate way could be read to claim the drug product ACTOS, but aware that sales from its promising new ACTOS franchise would likely be wiped out by generic entry upon the expiration of the '777 ACTOS Compound Patent – Takeda filed false or misleading information with the FDA stating that the '584 Met Combo Patent claimed both the "drug product" ACTOS and its "method of use." Takeda thereby caused the '584 Met Combo Patent to be listed in the Orange Book as claiming the ACTOS product (and not just the method of using ACTOS in combination with metformin). In doing so, Takeda knowingly and falsely submitted patent information to the FDA describing the '584 Met Combo Patent as a drug product patent *that claims ACTOS*.

171. When submitting the '584 Met Combo Patent information to the FDA, Takeda knew that the information was false and misleading. As a matter of law and fact, Takeda was not required to misrepresent to the FDA that the '584 patent covered the drug product ACTOS. Takeda acted with the purpose and effect of impairing competition from generic, and it did so for the specific purpose of seeking to extend its monopoly beyond January 17, 2011.

172. On December 11, 2001, the PTO issued U.S. patent No. 6,329,404 (the "'404 Insulin Combo Patent") entitled "Pharmaceutical Composition." The patent was assigned to Takeda Chemical Industries, Ltd. and later to a different Takeda entity. The '404 Insulin Combo Patent purports to claim a pharmaceutical composition comprising pioglitazone or salts

thereof *in combination with* an insulin secretion enhancer (*e.g.*, a sulfonylurea, such as glimepiride) and methods for treating diabetes which comprise administering a therapeutically effective amount of pioglitazone or salts thereof in combination with an insulin secretion enhancer. The '404 Insulin Combo Patent expires on June 19, 2016.

173. The '404 Insulin Combo Patent did *not* claim the compound pioglitazone (the active ACTOS drug ingredient); at most, the '404 Insulin Combo Patent claims a method of using pioglitazone in combination with another active ingredient, an insulin secretion enhancer (*e.g.*, a sulfonylurea, such as glimepiride). As a result, the '404 patent does not conceivably cover a standalone pioglitazone drug product, and thus would not cover the drug product ACTOS. As to ACTOS, the '404 Insulin Combo Patent was at most only a method-of-use patent, and not a drug product or composition patent for ACTOS.[60]

174. As such, a lawfully accurate listing in the Orange Book would list the '404 Insulin Combo Patent as only a method-of-use patent under the ACTOS NDA listed drug status. In doing so, any ANDA applicant could take advantage of the section viii statement path contemplated by Hatch Waxman to encourage the introduction of non-infringing uses of a drug. Here, that would mean that upon the expiration (in January of 2011) of the drug product patent for ACTOS (the '777 patent), generics could obtain final FDA approval for generic ACTOS even though patents still covered the combination of ACTOS with insulin (because that generic would carve-out of its label the combination use). In this way, the insulin

[60] The '404 Insulin Combo Patent only potentially covers a combination product using both pioglitazone and an insulin secretion enhancer. As such, the '404 Insulin Combo Patent arguably covers as a product what eventually would be sold by as Duetact (not ACTOS or ACTO*plus* met) – the purported commercial embodiment of the '404 Insulin Combo Patent.

combination method-of-use claims for ACTOS would not stand in the way of the introduction of generic ACTOS for non-combination use with insulin.

175. Takeda knew this. But rather than file lawfully accurate information with the FDA for Orange Book listing purposes, it misrepresented the scope of the '404 Insulin Combo Patent.

176. On or about January 3, 2002 – and despite knowing that its newly acquired '404 Insulin Combo Patent could in no legitimate way be read to cover ACTOS, but aware that the huge sales Takeda was now achieving from its ACTOS franchise (now two years in and booming) would likely be wiped out by generic entry upon the expiration of the '777 ACTOS Compound Patent – Takeda submitted false or misleading patent information with the FDA stating that the '404 Insulin Combo Patent claimed both the "drug product" ACTOS and a "method of use" for it, and Takeda thereby caused the '404 Insulin Combo Patent to be listed in the Orange Book as covering the drug product ACTOS.

177. In doing so, Takeda knowingly and falsely submitted patent information to the FDA describing the '404 Insulin Combo Patent as a drug product patent *that claims ACTOS*. As a matter of law and fact, Takeda was not required to misrepresent to the FDA that the '404 patent covered the drug product ACTOS. Takeda acted with the purpose and effect of impairing competition from generic, and it did so for the specific purpose of seeking to extend its monopoly beyond January 17, 2011.

178. In addition to the '777 ACTOS Compound Patent, the '584 Met Combo Patent, and the '404 Insulin Combo Patent, Takeda submitted eight other patents to the FDA for listing in the Orange Book:

Patent No.	Issue Date	Patent Expiry
6,150,383 (the "'383 Patent")	November 21, 2000	June 19, 2016
6,150,384 (the "'384 Patent")	November 21, 2000	June 19, 2016
6,166,042 (the "'042 Patent")	December 26, 2000	June 19, 2016
6,166,043 (the "'043 Patent")	December 26, 2000	June 19, 2016
6,172,090 (the "'090 Patent")	January 9, 2001	June 19, 2016
6,211,205 (the "'205 Patent")	April 3, 2001	June 19, 2016
6,271,243 (the "'243 Patent")	August 7, 2001	June 19, 2016
6,303,640 (the "'640 Patent")	October 16, 2001	August 9, 2016

These patents (the "ACTOS Method-of-Use Patents") claimed various methods of using ACTOS in combination with other drug products (such as biguanide or an insulin secretion enhancer) to treat various conditions or to reduce various side effects. Unlike the '584 Met Combo Patent and the '404 Insulin Combo Patent (which Takeda falsely listed in the Orange Book as covering the ACTOS drug product when both, in fact, were limited method of use patents), Takeda listed all of these additional ACTOS Method-of-Use Patents in the Orange Book only as method of use patents, not drug substance or drug product patents.

179. Under both the Hatch-Waxman Act and the FDA's implementing regulations, the drug product claims of the '584 Met Combo Patent and the '404 Insulin Combo Patent do not form a permissible basis for Takeda to submit patent information describing the patents as drug product patents covering ACTOS.

180. *First*, Takeda could properly identify the '584 and '404 patents as drug product patents claiming ACTOS only if the patents in fact claimed the ACTOS drug product. The patents unequivocally do not do so. The *only* active ingredient in ACTOS is pioglitazone hydrochloride. By contrast, the drug product claims in the '584 Met Combo Patent and the '404 Insulin Combo Patent claim drug products containing *both* pioglitazone *and* certain additional active ingredients—biguanide or an insulin secretion enhancer, respectively. Neither

patent claims a drug product that contains pioglitazone as its sole active ingredient. Thus, the patents do not claim the ACTOS drug product as a matter of law.

181. *Second*, Takeda could not reasonably assert the drug product claims of the '584 '404 patents against generic drug manufacturers seeking to market ACTOS. The patents claimed only drugs *other* than the ACTOS drug product. In fact, it would be impossible for any ANDA referencing the ACTOS NDA to get FDA approval of a drug containing either of the compositions claimed in the '584 and '404 patents. (In patent litigation to be described below, Takeda would eventually concede the inapplicability of the '584 and '404 drug product claims to ACTOS generics when it withdrew infringement claims based on those claims before a court could rule on them).

182. Takeda's intentionally wrongful identification in the Orange Book of the '584 and '404 patents as covering the drug product ACTOS (rather than just a method of using ACTOS in combination with either metformin or insulin) had several impacts on the regulatory paths available for generic entry.

183. *First*, a would-be maker for generic ACTOS aware that Takeda had listed the '584 Met Combo Patent and '404 Insulin Combo Patent as claiming the drug product ACTOS (rather than just a method of using ACTOS) would be required, when making its ANDA filing, to make a certification under Paragraph III or IV; a section viii statement as to the purported drug product claims covering ACTOS would not be available; and the applicable certification would be a paragraph IV certification that the drug product claims in the '584 and '404 patents were invalid, unenforceable, or not infringed. (In contrast, if Takeda had listed the '584 and '404 patents as applicable to ACTOS only as method-of-use patents, an ANDA filer could choose the section viii statement route to gain expedited approval for non-infringing uses, and

the '584 and '404 patents would not be a bar to FDA final approval upon lapse of the '777 patent at the end of January 2011).

184. *Second*, once the paragraph IV certification was made, Takeda would be able to file an infringement lawsuit based on the technical act of infringement, and a would-be generic maker proceeding by way of a paragraph IV certification would be blocked from FDA approval until expiration of the automatic 30-month stay.[61] (In contrast, if Takeda had listed the '584 and '404 patents as applicable to ACTOS only as method-of-use patents, and the ANDA filer chose the section viii route, then there would be no opportunity to block generic entry through use of the automatic 30-month stay).

185. *Third*, the fact that the patents had been (incorrectly) listed as claiming ACTOS as a product with a consequent paragraph IV certification meant that, with that paragraph IV certification, the *first* generic applicant(s) to file an ANDA would gain the 180-day exclusivity for ANDA-approved ACTOS generics, and no other generics could then be granted FDA final approval until the 180-day exclusivity lapsed, was waived, or was revoked. In effect, the wrongful listing of the '584 and '404 patents created an opportunity for one (or more) first filer generics to enjoy a 180-day exclusivity right (and ability to bottleneck competitors' applications) for ACTOS that otherwise would not have existed if the patents had been listed correctly under the ACTOS NDA as just covering the particular methods of using ACTOS.

186. Takeda did not just knowingly submit false or misleading patent information about the '584 Met Combo Patent and the '404 Insulin Combo Patent to the FDA in 1999 and

[61] As described later, plaintiffs are *not* complaining that the 30-month stay here delayed the approval of generic Actos. Rather, the alleged harm is that Takeda caused generic delay because it created a false 180-day exclusivity by providing false patent information, which lead to an incorrect Orange Book listing; and by creating the exclusivity (which the first wave generics later acquired as a result of filing paragraph IV certifications), Takeda was able to delay other generics from the market and then use the existence of 180 day exclusivity as a tool when later negotiating settlements with the three first wave generics.

2002. Takeda repeatedly misrepresented that these patents claimed the drug product ACTOS (rather than just a methods of using ACTOS), including in supplemental FDA Forms 3542 filed after the regulations were amended in 2003. Takeda was required to provide specific patent information (described above) following approval of 2003 and 2007 ACTOS NDA supplements, and each time reaffirmed Takeda's claim that the '584 and '404 patents both claim the drug product ACTOS.

187. To be very clear: Takeda's wrongful Orange Book listing is a stand-alone antitrust violation under traditional rule-of-reason law, regardless of whether the later pacts are also anticompetitive. Takeda violated Sherman Act §2 by undertaking that wrongful listing and maintaining that listing over time. And plaintiffs assert an independent monopolization claim against Takeda.

C. The first wave of ACTOS generic applications are filed.

188. Generic drug manufacturers were eager to apply for FDA approval to market generic versions of ACTOS.

189. On July 15, 2003 – the first day generics could do so given the NCE status of ACTOS – four generic manufacturers, Mylan, Alphapharm (which Mylan subsequently acquired in 2007, and thus the facts as they relate to Alphapharm are not separately alleged in this complaint), Ranbaxy, and Actavis, each filed an ANDA seeking FDA approval to manufacture, market, and sell generic ACTOS.

190. Of course, Mylan, Ranbaxy, and Actavis are separate generic companies, and they are supposed to be *competitors* with each other, and with Takeda. Their ANDAs were filed on the same day because that is the earliest date each of them, acting separately, could do so,

and because (at least at this time) they were acting as generic makers should – seeking to enter the market as early as they can, and ahead of the competition.

1. Mylan ANDA.

191. The Mylan ANDA, which was assigned ANDA No. 076801, contained a paragraph IV certification as to the '777 ACTOS Compound Patent, the '584 Met Combo Patent, and the '404 Insulin Combo Patent, and section viii statements as to the ACTOS Method-of-Use Patents.

192. By letter dated September 8, 2003, Mylan notified Takeda that Mylan had filed ANDA No. 076801 seeking to manufacture, market, and sell a generic version of ACTOS and that the ANDA contained a paragraph IV certification as to the '777 ACTOS Compound Patent, '584 Combo Patent, and '404 Insulin Combo Patent, and section viii statements as to the ACTOS Method-of-Use Patents.

2. Actavis ANDA.

193. As accepted for filing by the FDA, the Actavis ANDA, which was assigned ANDA No. 076798, contained a Paragraph III certification as to the '777 ACTOS Compound Patent, a paragraph IV certification as to the '584 and '404 patents, and section viii statements as to the ACTOS Method-of-Use Patents.

194. By letter dated September 9, 2003, Actavis notified Takeda that Actavis had filed ANDA No. 076798 seeking to manufacture, market, and sell a generic version of ACTOS and that the ANDA contained a Paragraph III certification as to the '777 ACTOS Compound Patent, a paragraph IV certification as to the '584 and '404 patents, and section viii statements as to the ACTOS Method-of-Use Patents.

3. Ranbaxy ANDA.

195. The Ranbaxy ANDA, which was assigned ANDA No. 076800, contained a Paragraph III certification as to the '777 ACTOS Compound Patent, a paragraph IV certification as to the '584 and '404 patents, and section viii statements as to the ACTOS Method-of-Use Patents.

196. By letter dated September 18, 2003, Ranbaxy notified Takeda that Ranbaxy had filed ANDA No. 076800 seeking to manufacture, market, and sell a generic version of ACTOS and that the ANDA contained a Paragraph III certification as to the '777 ACTOS Compound Patent, a paragraph IV certification as to the '584 and '404 patents, and section viii statements as to the ACTOS Method-of-Use Patents.

D. The Mylan, Ranbaxy and Actavis 180-day exclusivity created by Takeda's false Orange Book listings.

197. As a result of these filings, each of the first wave generics – Mylan, Ranbaxy and Actavis – addressed the impediments presented by the wrongful Orange Book listings of the '584 Met Combo Patent and the '404 Insulin Combo Patent as claiming the ACTOS product by submitting paragraph IV certifications as to those product claims. By doing so, each acquired a right that they would not otherwise have had were it not for Takeda's wrongful listing of those patents as covering the ACTOS product – the right to be treated as "first-to-file" ANDA applicants entitled to enjoy 180-day exclusivity from other generic company ANDA-approved sales, and the ability to bottleneck the entry of other generics (subject to certain exceptions, which will be addressed later) until such time as one of these first wave filers chose to launch its generic. The FDA ultimately concluded that Mylan, Ranbaxy, and Actavis were entitled to "shared" 180-day exclusivity with respect to generic ACTOS; each had first-to-file exclusivity (subject to exceptions) from non-first wave generic makers for the first six months from when

the first of any one of the first wave filers chose to launch their generic product (assuming the company had final approval from the FDA, of course). This status was only available under the '584 and '404 patents by reason of Takeda's false listing of those patents as claiming the ACTOS product.

198. On October 17, 2003, Takeda filed three separate suits in the United States District Court for the Southern District of New York: *Takeda Chemical Industries, Ltd, et al. v. Ranbaxy Laboratories, Ltd, et al.*, Civil Action No. 1:03-cv-08250-DLC (S.D.N.Y.); *Takeda Chemical Industries, Ltd., et al. v. Mylan Laboratories Inc., et al.*, Civil Action No. 1:03-cv-08253-DLC (S.D.N.Y.); and *Takeda Chemical Industries, Ltd, et al. v. Watson Pharmaceuticals, Inc., et al.*, Civil Action No. 1:03-cv-08254-DLC (S.D.N.Y.). Filing the lawsuits triggered 30-month stays, but the stays expired before the '777 ACTOS Compound Patent (which plaintiff here do not challenge), so the stay did not delay generic entry.

199. Takeda alleged that Ranbaxy's, Mylan's, and Actavis' generic ACTOS products would induce infringement of claims of the '584 Met Combo Patent and '404 Insulin Combo Patent, pursuant to 35 USC § 271(e)(2)(A), and induce infringement of the method-of-use claims of the '584 and '404 patents and certain of the ACTOS Method-of-Use Patents, pursuant to 35 USC § 271(b). Takeda also alleged that Mylan's generic ACTOS product would infringe the '777 ACTOS Compound Patent, pursuant to 35 USC § 271(e)(2)(A). Takeda filed the patent infringement cases against Mylan, Actavis, and Ranbaxy without regard to the merits of the cases with respect to the '584 Met Combo Patent and '404 Insulin Combo Patent.

200. The fact that Takeda asserted only inducement infringement theories against the first wave generics on the '584 and'404 patents carries an implicit recognition that no colorable direct claim for infringement would rest by the manufacture or sale of a generic

ACTOS by itself. The '584 and '404 patents did not claim the drug product ACTOS. Takeda knew no justifiable basis existed to report the '584 and '404 patents to the FDA as claiming the ACTOS product.

201. Takeda's induced infringement claims, their only infringement claims, were weak. Intent to induce infringement cannot be inferred, not even when the alleged inducer (here, a generic) has actual knowledge that some users of its product may actually infringe the patent. Takeda would have to prove, at trial, that one or more would be infringer actually made statements or took actions promoting infringement. Namely, that a generic company launching a generic Actos product that carves out method of use claims took active steps to encourage using its product in combination with metformin or insulin – *e.g.*, advertising combination use, or instructing how to use its product in a combination. Takeda would not have been able to prove active steps taken to encourage direct infringement that would have been necessary to show an affirmative intent that the product be used in an infringing manner.

202. During the litigation, Mylan, Actavis, and Ranbaxy secured substantial evidence via discovery supporting a host of defenses focusing on the non-enforceability and invalidity of the '584 and '404 patents, and on the weakness of Takeda's infringement allegations regarding those patents and the ACTOS Method-of-Use Patents. And during pretrial proceedings Takeda affirmed that it was making no allegations that Mylan, Actavis, and Ranbaxy's generic ACTOS products infringed the drug product claims of the '584 Met Combo Patent and '404 Insulin Combo Patent.

E. The Teva generic ACTOS application is filed.

203. In the 2000s, Israel-based Teva had grown to become one of the world's largest drug makers, focusing on finished generic products.

204. On or around July 14, 2004, Teva filed ANDA No. 077210, seeking to manufacture, market, and sell generic versions of ACTOS.

205. The Teva ANDA contained a Paragraph III certification as to the '777 ACTOS Compound Patent, which meant Teva would not seek to market its generic product before the January 17, 2011 expiration of the patent. Teva did not, however, to submit a paragraph IV certification with respect to either the '584 Combo Patent or the '404 Insulin Combo Patent. Instead, with respect to those patents, as well as the Method-of-Use Patents, Teva included only section viii statements.[62] As permitted by applicable regulations, the section viii statements asserted that Teva's label for its generic ACTOS would "carve out" information regarding methods of using ACTOS in combination with a biguanide or an insulin secretion enhancer (the methods of use claimed by the '584 Combo Patent and '404 Insulin Combo Patent, respectively) or other uses covered by the Method-of-Use Patents.

206. Teva's decision not to include a paragraph IV certification with respect to the '584 and '404 patents raised the potential that the FDA could approve Teva's ANDA without regard to whether any other ANDA applicant was otherwise entitled to a 180-day exclusivity period with respect to ACTOS. Teva could accomplish this in one of two ways: either the FDA would determine (without court proceedings) that the section viii statement was sufficient (and not give credence to the product listing as to ACTOS in some way), or (if the FDA was unwilling to do so), a court would determine the listing incorrect and require correction under § 355(j)(5)(C)(ii). Under either path, a road for FDA to approve Teva's ANDA without regard to any 180-day exclusivity would exist.

[62] It appears that at the time of filing its ANDA, Teva may have read the Orange Book listings as only containing a listing as to the method-of-use claims in the '584 and '404 patents. Teva would later argue in 2010 that Takeda had only recently added the product claims to the '584 and '404 listing information.

207. In other words, Teva's section viii strategy set up the real potential for Teva to leap frog over the first wave ACTOS generic filers – Mylan, Ranbaxy, and Actavis – and launch a generic version of ACTOS once the '777 ACTOS Compound Patent expired in January 2011. And this is exactly how the Hatch Waxman laws and regulations are supposed to work for the entry of generic drugs when later, method-of-use patents might hinder generic entry – so long as the ANDA applicant can get approval of a section viii statement in which the applicant carves out the patented method of sue, the generic product can be approved by the FDA and launched into the market for non-patented uses. And it may do so regardless of any 180-day exclusivity another ANDA applicant may have for the patented method-of use.

208. Because the Teva ANDA did not contain a paragraph IV certification with respect to any Orange Book-listed patent for ACTOS, Teva was not required to, and so did not, send a notice letter to Takeda regarding the Teva ANDA.

209. In or about February 2006, Teva received tentative approval from the FDA for its ACTOS ANDA. By doing so, the FDA accepted Teva's section viii statement and carved-out labeling of the ostensibly patented methods of using ACTOS with metformin and insulin.

F. The challenge to the '777 ACTOS Compound Patent is tried.

210. Following discovery, the Takeda actions against Mylan, Ranbaxy and Actavis were consolidated. The court hearing the consolidated action opted to try Mylan's challenge to the '777 ACTOS Compound Patent before considering the other asserted patents.

211. After a bench trial held in January 2006, the court found that the '777 ACTOS Compound Patent was not invalid due to obviousness and that Takeda had not engaged in

inequitable conduct in obtaining the patent.[63] This decision was upheld by the United States Court of Appeals for the Federal Circuit in June 2007.[64]

212. The decision on the '777 ACTOS Compound Patent had no bearing to the merits of Takeda's infringement claims based on the '584 Met Combo Patent and '404 Insulin Combo Patent, nor did it have any bearing on whether Takeda had wrongfully caused those patents to be listed in the Orange Book as claiming the ACTOS drug.

G. Takeda gains approval for ACTO*plus* met and launches the product.

213. By the fall of 2004, Takeda's efforts to find a line extension product for ACTOS had developed a combination product using both pioglitazone and metformin.

214. On October 27, 2004, Takeda submitted NDA 021842, seeking FDA approval to manufacture, market, and sell a fixed single dose combination tablet of pioglitazone hydrochloride and metformin hydrochloride designed to improve glycemic control in adults with Type 2 diabetes, which Takeda subsequently marketed as ACTO*plus* met.

215. On August 29, 2005, the FDA approved Takeda's NDA for ACTO*plus* met. Takeda listed the '584 Met Combo Patent in the Orange Book as a drug product patent for ACTO*plus* met, and listed three additional patents – the '042 Patent, the '043 Patent, and the '090 Patent – as applicable method-of-use patents (the "ACTO*plus* met Method-of-Use Patents"). Each of the ACTO*plus* met Method-of-Use Patents are also listed as one of the ACTOS Method-of-Use Patents.

216. ACTO*plus* met quickly grew to become one of Takeda's most profitable drugs. By 2012, the product delivered more than $413 million in annual sales to Takeda.

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[63] *Takeda Chem. Indus., Inc. v. Mylan Labs., Inc.*, 417 F. Supp. 2d 341 (S.D.N.Y. 2006).

[64] *Takeda Chem. Indus., Inc. v. Alphapharm Pty., Ltd.*, 492 F.3d 1350 (Fed. Cir. 2007).

H. The first generic ACTO*plus* met generic application.

217. On or about March 5, 2008, Mylan filed an ANDA seeking FDA approval to manufacture, market, and sell generic ACTO*plus* met. The Mylan ANDA, which was assigned ANDA No. 090406, contained a paragraph IV certification as to the '584 Met Combo Patent and the ACTO*plus* met Method-of-Use Patents.

218. By letter dated June 23, 2008, Mylan notified Takeda that Mylan had filed ANDA No. 090406, seeking to manufacture, market, and sell a generic version of ACTO*plus* met, and that the ANDA contained a paragraph IV certification with respect to the '584 Met Combo Patent and the ACTO*plus* met Method-of-Use Patents. Mylan was the first ANDA filer to submit a substantially complete ANDA with a paragraph IV certification to market generic ACTO*plus* met.

219. On August 5, 2008, Takeda filed suit in the United States District Court for the Southern District of New York, *Takeda Pharmaceutical Co. Ltd., et al. v. Mylan Laboratories Inc., et al.*, Civil Action No. 1:08-cv-06999-DLC (S.D.N.Y.), alleging that Mylan's ANDA for generic ACTO*plus* met directly infringed, intentionally induced infringement, and/or contributed to the infringement of the '584 Met Combo Patent and two of the three ACTO*plus* met Method-of-Use Patents.

220. Takeda filed the patent infringement case against Mylan without regard to the merits of the case. Simply by filing the lawsuit, Takeda obtained the automatic exclusion of Mylan from the market for thirty months and the ability to create a 180-day exclusivity bottleneck.

221. During the litigation, Mylan conducted discovery supporting a host of defenses focusing on the non-enforceability, invalidity, and weaknesses in Takeda's indirect and

contributory patent infringement allegations for the '584 Met Combo Patent and the asserted ACTO*plus* met Method-of-Use Patents.

I. The Teva generic ACTO*plus* met application.

222. In late 2008 or early 2009, Teva filed an ANDA seeking FDA approval to manufacture, market, and sell generic ACTO*plus* met. The Teva ANDA, which was assigned ANDA No. 091155, contained a paragraph IV certification as to the '584 Met Combo Patent and the ACTO*plus* met Method-of-Use Patents.

223. By letter dated April 14, 2009, Teva notified Takeda that Teva had filed ANDA No. 091155, seeking to manufacture, market and sell generic versions of ACTO*plus* met and that the ANDA contained a paragraph IV certification as to the '584 Met Combo Patent and the ACTO*plus* met Method-of-Use Patents.

224. On May 18, 2009, Takeda filed suit against Teva in the United States District Court for the Southern District of New York, *Takeda Pharmaceutical Co. Ltd., et al. v. Teva Pharmaceutical Industries, Ltd., et al.*, Civil Action No. 1:09-cv-04665-DLC (S.D.N.Y.), alleging that Teva's ANDA for generic ACTO*plus* met directly infringed, intentionally induced infringement, and/or contributed to the infringement of the '584 Met Combo Patent and two of the three ACTO*plus* met Method-of-Use Patents. Takeda also alleged that ANDA No. 077210, Teva's ANDA for ACTOS, induced infringement of the '584 and '404 patents, and five of the ACTOS Method-of-Use Patents. Takeda filed the lawsuit without regard to its merits. Takeda did so knowing that it had no realistic expectation of success on the merits of its claims and with the intent to hinder competition.

225. In July 2009, Takeda's lawsuit against Teva was consolidated with the Takeda lawsuits against Mylan, Ranbaxy and Actavis.

226. Takeda's ACTOS infringement claims under the '584 and '404 patents were based solely on the theory that the launch of an ACTOS generic would *induce* use of the product for combination use with metformin or insulin, and were therefore weak. Teva's ANDA had expressly disclaimed those uses; the FDA had tentatively approved that ANDA, documenting acceptance of the carve-out. There was nothing inherent in the use of generic ACTOS that would require its use with metformin or insulin. Nor had Takeda demonstrated in any public court filing that it had any evidence of intent (as required by law) on the part of Teva to encourage the infringing use. In the absence of the December 2010 pact, there is every reason to believe that Teva should be taken at the word of its March 30, 2010 filing – that it intended to secure approval for, and launch, generic ACTOS at the end of January 2011.[65]

J. Other generic manufacturers file ANDAs for generic ACTOS and ACTO*plus* met.

227. While the Takeda litigation against Mylan, Actavis, Ranbaxy and Teva regarding their ANDAs for ACTOS continued, other generics filed ANDAs for generic ACTOS that contained paragraph IV certifications as to some or all of the Orange Book-listed patents for ACTOS. These generics notified Takeda of their respective ANDAs and the paragraph IV certifications contained therein, and Takeda filed suit against each of these generics, alleging infringement of the '584 Met Combo Patent, the '404 Insulin Combo Patent and certain of the ACTOS Method-of-Use Patents:

[65] The strength of an induced infringement argument may vary from alleged inducer to alleged inducer, as it relates to statements or actions taken by the alleged inducer. If, for example, an alleged inducer did not carve out uses, it may be easier to allege induced or actual infringement. Plaintiffs allege that as to the first wave generics and Teva, specifically, Takeda's induced infringements claims were weak.

Generic	ANDA No.	Date Sued
Sandoz, Inc.	078670	May 16, 2007
Torrent Pharmaceuticals Ltd.	091298	July 22, 2009
Aurobindo Pharma Ltd.	200268	January 13, 2010
Dr. Reddy's Laboratories Ltd.	078383	May 20, 2010
Wockhardt Ltd.	078038	July 28, 2010
Synthon Pharmaceuticals, Inc.	078472	September 8, 2010
Zydus Pharmaceuticals USA, Inc.	202456	January 14, 2011
Apotex, Inc.	202502	March 4, 2011
Macleods Pharmaceuticals Ltd.	202467	May 6, 2011
Accord Healthcare, Inc.	200044	September 12, 2011
Hetero Drugs Ltd.	293467	November 16, 2011

228. Likewise, after Mylan and Teva filed their ANDAs for generic ACTO*plus* met, additional ANDAs for generic ACTO*plus* met were filed by Sandoz, Inc. (ANDA 091273) and Aurobindo Pharma Ltd. (ANDA No. 200823) containing paragraph IV certifications as to the Orange Book-listed patents for ACTO*plus* met. Takeda filed suit against Sandoz on June 3, 2009 and against Aurobindo on February 18, 2010.

K. Takeda wrongfully maintains the Orange Book listings for ACTOS as including drug product claims in the '584 and '404 patents.

229. Since the time that Takeda had listed the '584 Met Combo Patent and the '404 Insulin Combo Patent in the Orange Book back in October 1999 and January 2002, Takeda wrongfully used those listings over the years as covering the ACTOS drug product, and it repeatedly reiterated its untruthful position that those limited method of use patents claim the ACTOS drug product (as opposed to only claiming particular methods of using ACTOS).

230. For example, Takeda reiterated to the FDA its claim that the '584 and '404 patents both claim the drug product ACTOS. The 2003 amendments to 21 CFR § 314.52 required Takeda to provide "an accurate and complete submission of patent information" following approval of each supplemental NDA submission it made.[66] Takeda filed numerous supplements to NDA 21-073 for ACTOS, e.g., Supplement No. 020 approved by the FDA on November 26, 2003 and Supplement No. 026 approved by the FDA on February 25, 2007. Takeda was required to submit a FDA Form 3542 following FDA approval of each of these supplemental NDAs, and each of these forms reaffirmed Takeda's claim that the '584 and '404 patents both claim the drug product ACTOS.

231. Takeda also had used the wrongful listings to invite paragraph IV certifications by first wave generic filers for generic ACTOS.

232. On or about January 22, 2010 (and continuing its conduct of using the wrongful listings to gain anticompetitive advantage), Takeda responded to a citizen petition submitted to the FDA by Sandoz, another generic drug manufacturer that had filed an ANDA for generic ACTOS. Teva had asserted that Takeda had improperly caused the FDA to list the '584 and '404 patents in the Orange Book as drug product patents for ACTOS. In its comment to the petition, dated January 22, 2010, Takeda "confirm[ed] for FDA the listing of [the '584 Met Combo Patent and '404 Insulin Combo Patent] under the terms described in Takeda's original

[66] *See* 21 CFR § 314.53(c)(ii) (2003) ("Within 30 days after the date of approval of its application or supplement, the applicant shall submit FDA Form 3542 for each patent that claims the drug substance (active ingredient), drug product (formulation and composition), or approved method of use."); Applications for FDA Approval to Market a New Drug: Patent Submission and Listing Requirements and Application of 30-Month Stays on Approval of Abbreviated New Drug Applications Certifying That a Patent Claiming a Drug Is Invalid or Will Not Be Infringed (68 FR 36676, at 36710 (June 18, 2003)), FDA Form 3542 ("This patent declaration form is required to be submitted to the Food and Drug Administration (FDA) within thirty (30) days after approval of an NDA or supplement"); *id.*, at 36712 (Declaration Certification for FDA Form 3542, requiring the NDA holder to certify that "this is an accurate and complete submission of patent information for the NDA or supplement approved under section 505 of the Federal Food, Drug, and Cosmetic Act.").

patent submissions." Takeda argued that it "characterized them for FDA in the appropriate patent declarations as containing both 'Drug product' and 'Method of use' claims," and that "[s]ince the original submission of these patents to FDA, Takeda has continued to certify to the applicability of the patents to ACTOS under the original declarations…."

233. Although Takeda's statements that it had continued to certify, over the years, the '584 and '404 patents as claiming the drug product ACTOS were true (i.e., it had continued this form of patent information to the FDA), that information was false and misleading. Neither patent claimed the drug product ACTOS; they only claimed particular methods of using ACTOS. While the patents did claim combination products, neither claimed the drug product ACTOS.

234. In a ruling on the citizen petition, dated March 15, 2010, the FDA confirmed that Takeda's original patent information had indeed "stated that the patents claimed both the drug product and a method of use." The FDA further concluded that "[i]n keeping with our practice of relying solely on the NDA sponsor's patent declaration describing relevant patent claims in Orange Book-listed patents, FDA will rely on Takeda's patent declarations submitted to FDA." The FDA specifically noted that Takeda's January 22, 2010 comment to the citizen petition had "reconfirm[ed]" the original listing. But whether this patent information was correct or false was not an issue to be addressed by the FDA. Instead, "FDA's role in listing patents and patent information in the Orange Book is ministerial," and "FDA relies on the NDA sponsors to provide an accurate patent submission."

235. The FDA concluded that, because Takeda had submitted patent information describing the '584 Met Combo Patent and '404 Insulin Combo Patent as claiming the ACTOS drug product, all ANDA filers seeking approval to market generic ACTOS before the expiration of the patents were required to submit paragraph IV certifications as to those

product claims, rather than section viii statements. The requirement that Teva and all ANDA filers submit paragraph IV certifications to the product claims – and thereby become subject to the first-filer's 180-exclusivity – resulted from Takeda's false description of the '584 and '404 patents as drug product patents claiming ACTOS (notwithstanding that neither patent in fact claimed ACTOS). The FDA concluded that, "it is the patent declaration submitted by the NDA holder and any subsequent amendments or supplements to that declaration that controls FDA's listing of patents and patent information. In keeping with our practice of relying solely on the NDA sponsor's patent declaration describing relevant patent claims in Orange Book-listed patents, FDA will rely on Takeda's patent declarations submitted to FDA."

236. The decision of the FDA on the petition was not a ruling as to the accuracy (or lack thereof) of Takeda's patent information provided for the '584 and '404 patents. In fact, the FDA – as has long been the case – indicated explicitly that it was bound to accept the representations made by Takeda. Instead, the vehicle by which to address the false and misleading information provided by Takeda was through a counterclaim in accordance with 21 U.S.C. § 355(j)(5)(C)(ii).

237. On March 30, 2010, Teva filed a supplemental answer and counterclaim in the suit brought against it by Takeda seeking relief under the counterclaim provision of the 2003 amendments to Hatch-Waxman, 21 U.S.C. § 355(j)(5)(C)(ii). Teva sought an order "to correct certain false, misleading, and/or incorrect information Takeda recently submitted to FDA concerning two patents in connection with the Orange Book listings for the NDA for Takeda's Actos® product." As it stated:

> Back in "November 2009 and January 2010 . . .Takeda [had] submitted information to FDA stating that the ['584 and '404] patents . . . contain drug product claims as well [as method-of-use claims]. Takeda pointedly failed to tell FDA, however, that the drug product claims in those two patents do *not* cover the Actos®

drug product. As a result, Takeda's submissions gave the strong – but false – impression that the drug product claims in those patents do cover Actos®. FDA did not separately analyze whether the patents properly claim the Actos® drug product. Instead, acting in a purely ministerial capacity consistent with its policy and practice, FDA deferred entirely to Takeda's submission in that regard.

Because FDA (in reliance on Takeda's submissions) now treats the '584 and '404 patents as containing both drug product claims and method-of-use claims that claim Actos®, FDA has stated that an ANDA applicant for a generic version of Actos® must submit a paragraph IV certification to the drug product claims if – as Teva has – it has submitted a section viii statement to the method-of-use claims. Without a paragraph IV certification, FDA now states, an ANDA for a generic version of Actos® cannot be approved.

Under both the Hatch-Waxman statute itself and the FDA's implementing regulations, the drug product claims for the '584 patent and the '404 patent do not form a permissible basis for listing those patents in the Orange Book in relation to the Actos® NDA. The drug product claims in those patents could properly be listed in the Orange Book for the Actos® NDA only if those patent claims in fact claimed the Actos® drug product. The patents unequivocally do not do so. The active ingredient in Actos® tablets is pioglitazone hydrochloride. . . .

[T]hose patents do not claim the Actos® drug product as a matter of law. Furthermore, because the drug product claims cannot be properly listed in relation to the Actos® NDA, there is no basis for requiring ANDA applicants for a generic version of Actos® to file a paragraph IV certification to those claims. . . .

The consequence of those incorrect listings – and the resulting directive by FDA that ANDA applicants must file paragraph IV certifications – will likely cause a substantial delay of approximately *two years* in FDA's approval for Teva's ANDA, from January 2011 (the expiration date of the drug substance patent covering pioglitazone) to February 2013 (the date on which any 180-day exclusivity would expire if first-filers launch in the August 2002 timeframe evidently specified in their settlements with Takeda). In addition, Takeda's wrongful conduct likely will mean that there will be *no* generic version of Actos® available to consumers for more than 18 months after such products otherwise would be available. By contrast, if Takeda were required to correct or delete the information it previously

> submitted to FDA, none of these improper delays would occur, and ANDAs for generic versions of Actos® could be approved in the manner and within the time frames that Hatch-Waxman actually contemplates.

L. The dynamics of competition in early 2010.

238. By early 2010 – and despite the false 180-day shared exclusivities for the frist wave generics made possible by Takeda's wrongful Orange Book listings – Takeda, the first wave generics (Mylan, Actavis and Ranbaxy), and Teva each faced competitive pressures produced by our free market system, the structure of competition established by the Hatch-Waxman Act, and laws fostering automatic substitution of brand drugs by FDA-approved generic equivalents upon expiry of valid patents.

239. As to Takeda, it was enjoying a $3 billion a year franchise for ACTOS and ACTO*plus* met, but time was quickly running out. The trial of the infringement suits for all these companies was scheduled for June 2010, and that date was firm. Rulings would issue before the date for expiry of the '777 patent in January of 2011. As to ACTOS, it faced generic challenges not only from the first wave generics and Teva, but also from over a half dozen other generics that were actively seeking FDA approval for generic ACTOS. Takeda's '777 ACTOS Compound Patent would expire on January 17, 2011, and unless Takeda was successful in leveraging the '584 Met Combo Patent and '404 Insulin Combo Patent to preclude any form of generic ACTOS entry (and not just ACTOS use in combination with metformin and insulin), generic ACTOS would hit the market by the end of January 2011. And Takeda faced the very real prospect of losing its ACTOS induced infringement claims. More on this later, but Takeda had every reason to expect it would lose the ACTOS induced infringement claims against at least Teva and likely others. As to ACTO*plus* met, Takeda similarly faced

powerful Mylan and Teva challenges to its assertions of patent exclusivity. The consequences of a loss would mean the absolute loss of the franchise.

240. The *lawful* settlement options of a reasonable, law-abiding brand company in the position of Takeda were to resolve each lawsuit separately with each generic maker, but do so based on the (limited) merits Takeda had in its inducement infringement claims for ACTOS and other claims for ACTO*plus* met, and *without* paying off the generic, *without* orchestrating future entry dates (or prices) amongst itself and its various generic competitors, and *without* leveraging the false Orange Book listings of the '584 and '404 patents as covering the ACTOS drug itself.

241. Acting in its own, independent economic interest, a reasonable, law-abiding brand company in the position of Takeda – a company neither unable to pay off its competitors, nor able to coordinate entry dates between its generic competitors, nor able to perpetuate a falsely-derived 180-day exclusivity for ACTOS – would accept some negotiated entry date for ACTOS generics not long after the January 17, 2011 expiry of the '777 patent. Such a settlement, even if only two weeks after expiry (to reflect the very small potential it had to show induced infringement by a generic ACTOS launch the FDA had already determined was legitimately capable of carving-out uses of ACTOS with metformin and insulin) would still yield it almost $100 million in gross sales. A reasonable, law-abiding brand company in the position of Takeda, acting in its own, independent economic interest, would settle the infringement actions and not run the risk of loss in litigation during 2010.

242. For Mylan and its ACTOS generic ANDA, Mylan faced competition on numerous fronts. First, Mylan faced competition from the two other generic manufacturers (Actavis and Ranbaxy) with whom it shared the falsely created, first-to-file 180-day exclusivity

for ACTOS product claims. Since both of those companies had pending ANDAs, either one or the other might seek to obtain FDA approval and launch its product as close to January 17, 2011 as possible; once it did so, the 180-day exclusivity period would be triggered, and Mylan would need to have obtained its FDA approval to launch at that time (or earlier, if it could beat to market the companies with whom it shared exclusivity). Second, Mylan faced competition from Teva (the largest of generic makers); Teva was pursuing a separate, rapid regulatory approach (the section viii approach) to gain FDA approval to launch generic ACTOS. If Teva were able to get a favorable ruling (from the FDA or a court) in 2010 on its section viii approach (a highly likely event given the clear lack of product claims for ACTOS in the '584 and '404 patents), then Teva would be able to immediately enter the market in late January 2011, and Mylan would lose the substantial economic benefit from its falsely created, 180-day exclusivity. Third, Mylan faced likely competition from Takeda because, upon generic entry and regardless of the 180-day exclusivity, Takeda would be able to launch an authorized generic product at any time, and thereby further reduce Mylan's market share and force further price pressure downwards. Fourth, Mylan faced competition from numerous other generic companies because, upon lapse of the 180-day exclusivity or a successful section viii launch by Teva, the ACTOS market would likely become inundated with multiple generic makers such that the entire ACTOS market would become wholly commoditized.

243. As for Mylan's ACTO*plus* met generic ANDA, while Mylan had the sole first-to-file exclusivity for ACTO*plus* met, it nevertheless faced significant competitive pressures. Mylan knew that upon generic entry Takeda would be able to launch an independent authorized generic. Mylan also knew that Teva was actively pursuing a generic ACTO*plus* met ANDA, and that Teva's legal position in the ACTO*plus* met infringement suit was so strong that there was a likely prospect that Teva would break the bottleneck of Mylan's sole

exclusivity (with enormous loss to Mylan). And Mylan knew that upon lapse of the 180-day exclusivity the ACTO*plus* met market would likely become inundated with multiple generic makers.

244. The *lawful* settlement option of a reasonable, law-abiding generic company in the position of Mylan was to resolve the ACTOS and ACTO*plus* met lawsuits with Takeda, but to do so separately from its generic competitors, *without* accepting payments from Takeda, *without* colluding with Takeda and the other two first wave generics to set future entry dates (or prices), and *without* structuring a settlement to maintain a 180-day exclusivity it knew was based on false Orange Book patent information.

245. Acting in its own, independent economic interest (and without colluding with its competitors), a reasonable, law-abiding generic company in the position of Mylan would seek an agreed entry date on or shortly after the January 17, 2011 for its generic ACTOS.

246. As for Actavis and Ranbaxy and their ACTOS ANDAs, they were in a similar position as Mylan. Each faced competition from the other generics with whom they shared 180-day exclusivity, faced the threats of Takeda's authorized generic, faced Teva's early entry generic threat (through the section viii approach on ACTOS), and faced the prospect of complete commoditization upon expiration of the 180-day exclusivity (or Teva's success with its section viii approach). Unlike Mylan, however, neither Actavis nor Ranbaxy had begun the process to address patent issues relating to ACTO*plus* met. Acting in their own, independent economic interest (and without colluding with their competitors), a reasonable, law-abiding generic company in the position of Actavis and Ranbaxy would each (separately) seek from Takeda an agreed entry date on or shortly after January 17, 2011.

247. And finally, Teva faced significant competitive pressures, but also had some advantages. As to Teva's ACTOS ANDA, while Teva knew that other generic companies had a falsely-created, shared 180-day exclusivity, it also knew it was pursuing generic ACTOS FDA approval through a section viii statement, and that if it were successful in doing so, the falsely-created 180-day exclusivities for its competitors would not be a bar to FDA approval of its generic ACTOS. Since Teva's approach would vitiate the 180-day stranglehold, Teva had strong economic incentive to pursue that approach and gain a period of *de facto* exclusivity for itself. As to Teva's ACTO*plus* met ANDA, Teva knew that Mylan held a sole 180-day exclusivity, but Teva also knew that it had strong legal arguments against Takeda's infringement claims such that it might break the bottleneck imposed by Mylan's exclusivity. In short, in early 2010 Teva was very much in a spoiler role, asserting significant pressure to gain timely generic entry by the end of January 2011. Acting in its own, independent economic interest (and without colluding with its competitors), a reasonable, law-abiding generic company in the position of Teva would seek an agreed entry date on or shortly after January 17, 2011 for its ACTOS generic.

M. Takeda orchestrates a group deal with the first wave generics, Mylan, Ranbaxy, and Actavis.

248. By mid-March of 2010, Takeda orchestrated a group deal in which all three of the first wave generics (Mylan, Actavis and Ranbaxy) settled litigation at the same time, in a coordinated way, and, essentially, as part of a single transaction (the "March 2010 pact").

249. Generally, the March 2010 pact structured agreements to benefit the first wave generics by (i) creating a major disincentive for Teva to continue its section viii efforts to enter the ACTOS market with a carved-out label, (ii) maintaining the falsely-created, shared 180-day exclusivity for the first wave ACTOS generics in order to keep the many other, later would-be

generics out of the market for the first six months of ACTOS launch, (iii) coordinating the timing of generic entry to ensure that all three (and potentially later Teva) would be entitled to enter the ACTOS market on the same date, and (iv) providing Actavis and Ranbaxy with additional, lucrative side deals as a further incentive to them to join the March 2010 pact.

250. In exchange, the three first wave generics agreed to delay launch of their generic ACTOS and ACTO*plus* met products for about a year and a half longer than would otherwise be expected to result from competition.

251. In reaching the March 2010 pact, Takeda and the first wave generics combined their efforts, and reached an overall agreement to allocate the markets for ACTOS and ACTO*plus* met, set uniform agreed entry dates between themselves, delay the entry of generics for both products, collude to protect their falsely-created, 180-day exclusivity the first wave generics had obtained through Takeda's wrongful Orange Book listings for product claims for ACTOS, and restrain Teva's effort to gain timely entry of generic ACTOS. Through market allocation, rather than market competition, each could make more and risk less.

252. The overall agreement was in reality a single deal between all four companies. Although they memorialized the agreement in separate written agreements between the companies, the agreements of each were part of a coordinated approach. The three generic companies were all involved in the same lawsuit. Takeda, faced the same mid-2010 trial date, and shared the same, falsely-based 180-day exclusivity for ACTOS generics. The settlements were announced within days of each other (March 10, 15 and 16), with announcements (for Ranbaxy and Actavis) that described the agreements in nearly identical language. The entry dates for all products were identical. The conditions of entry were identical, with the language for the coordinated entry dates nearly identical for all three. The terms of the agreements were

to be confidential, yet each agreement permitted Takeda to share the otherwise secret agreements with other generic competitors (a provision which could only exist if in fact it was planned to share the agreements between competitors). All three of the first wave generics knew that the Orange Book information describing the '584 and '404 patents as claiming the drug product ACTOS was false, that the ACTOS ANDA paragraph IV certifications as to those non-existent product claims (as opposed to the method-of-use claims) should have been unnecessary, and that therefore the 180-day exclusivity they enjoyed as a result rested on Takeda's misrepresentations to the FDA. And they knew the March 2010 pact was structured to maintain that false 180-day exclusivity for their benefit. None of the first wave generics would have agreed to the late entry dates for ACTOS and ACTOplus entry without knowing that their generic competitors were getting the same deal. And, as will be discussed, the terms of each of the agreements worked only if there were similar agreements with the others, containing nearly identical provisions and disincentives for independent actions.

253. In purpose and effect, the first wave generics – Mylan, Actavis and Ranbaxy – joined Takeda's long-term scheme to delay generic competition.

254. On or about March 15, 2010, Takeda entered into the March 2010 pact with each of Mylan, Actavis, and Ranbaxy. For ACTOS, the deal required Mylan, Actavis, and Ranbaxy to drop their challenges to the Takeda patents. Mylan, Ranbaxy, and Actavis agreed to delay launching their generic ACTOS products until August 17, 2012, or earlier under certain circumstances.

255. For ACTO*plus* met, Mylan agreed to drop its challenge to Takeda's patents and to keep its generic alternative out of the ACTO*plus* met market until December 14, 2012, or

August 17, 2012 if Takeda's sales of ACTO*plus* met dipped below a certain threshold (which they did).

256. As the *quid pro quo* for Mylan's, Actavis' and Ranbaxy's agreements to drop their challenges to the patents and delay entry for both products, Takeda gave Mylan, Ranbaxy, and Actavis each a package worth substantial sums, each taking several forms.

257. *First*, Takeda and the first wave generics shared the anticompetitive goal of terminating Teva's section viii carve-out launch for ACTOS. All four structured the March 2010 pact to create a major disincentive for Teva to continue its section viii efforts to enter the Actos market with a carved-out label. Takeda's agreement that, in the event any other generic ACTOS product entered the market before August 17, 2012, the agreed-upon entry dates for Mylan, Ranbaxy, and Actavis would be moved up correspondingly, created this disincentive.

258. The purpose and effect of these coordination clauses was to deter any other generic drug manufacturer from entering the market before then.

259. The first wave generics were aware of the terms of each other's agreement, and the execution of the agreements, and their terms, shows the agreements were interdependent. Each of the defendants was a knowing participant in the agreement and facilitated the scheme. It was not in the independent, self-interest of any of the first wave generics, or Teva, to delay its generic entry (for ACTOS, past the end of January of 2011; for ACTO*plus* met, past February of 2011) without being assured that the others would do the same. And when presented with the coordination clauses, each generic was offered an opportunity to engage in non-independent action – to coordinate the timing of entry with competitors. (None of the generics could be acting in their own, independent self-interest in agreeing to the coordination clauses, as the clauses themselves contemplate joint action).

260. Applied microeconomic theory, industry experience, and the facts as they played out for ACTOS and ACTO*plus* met products shows that the coordinated entry provisions had a significant deleterious impact on competition.

261. Under applied microeconomic theory, and as it is for the economic inferences used by the Supreme Court in *Actavis*,[67] the telling behavior is from the brand company, and what a rational brand company would do. The only reason a rational brand company would agree to a coordination clause that might (hypothetically) permit acceleration of competition is if the clause *reduces the likelihood of the competition* in the first place. Of course, the likelihood that a spoiler might be able to achieve the benchmarks needed to gain early entry depends on the facts of each case. And the extent to which coordination clauses might inhibit the interest of the spoiler in continuing efforts to achieve those benchmarks is also case dependent. But under microeconomic theory, the brand's agreement to the coordination clause means that in all cases the clause must reduce to some extent the likelihood of the spoiler continuing the chase.

262. Since these clauses are a form of a most favored nation's clause that, if hypothetically triggered, would work to the disadvantage of the party granting the MFN, then the grant must in some way also be working to the advantage of the brand. And industry experience also shows that the presence of coordination clauses for early-filed generics often work to have the later-filed generics drop patent challenges and simply accept the later-agreed entry dates.

[67] *FTC v. Actavis*, 133 S. Ct. 2223, 2235-2237 (2013)..

263. In this case, the fact is that the coordination clauses greatly reduced the likelihood of Teva continuing its efforts to be the spoiler through its section viii statement approach.

264. In this case the coordination clauses did not run just to the benefit of one generic entrant, but to three. Here, therefore, the extent to which the coordination clauses inhibited the interest of Teva (the spoiler) in continuing efforts to achieve early entry were greatly reduced due to the prospect that success in its section viii efforts would only mean that it would come into a market with at least three, and maybe more, other generics there too.

265. Teva had the strongest of section viii, § 355(j)(5)(C)(ii) counterclaims that might seek correction. There was no conceivable way for a court to conclude that the '584 Met Combo Patent or the '404 Insulin Combo Patent covered the drug product ACTOS. None. Nor was there any conceivable way for a court to conclude that the listing properly gave the FDA the impression these patents claimed the ACTOS drug product, or would require a paragraph IV certification requiring litigation of the combination patents in order to get just an ACTOS generic on the market with a carve-out for the combination use. And in March 2010 Teva was intent on pursuing its § 355(j)(5)(C)(ii) counterclaim, and it had a firm trial date of June of 2010 lined up (and reaffirmed by the district court judge). Yet despite the strength of its claim, and the imminence of a court determination, Teva would later in 2010 nevertheless compromise its position and agree to defer entry until late 2012. Its motivations *must* have changed in the wake of (confidential) disclosure to it of the coordination clauses.

266. The coordination clauses were intended to have, and had, significant, anticompetitive consequences. Eliminating the potential for Teva to enter the market before Mylan, Ranbaxy, and Actavis was of enormous benefit to the generics, but at great expenses to

purchasers because the clauses were a substantial cause for Teva's later agreement to delay entry until late 2012. The market for ACTOS brand products was in the billions of dollars; the market for a first entrant for ACTOS generics was in the hundreds of millions of dollars. Were Teva to succeed in its section viii statement efforts and beat the "first wave" generics to market, it would gain the lion's share of the market for itself – but Mylan, Ranbaxy, and Actavis would lose hundreds of millions of dollars.

267. *Second*, Takeda and the first wave generics shared the anticompetitive goal of perpetuating the false 180-day ACTOS exclusivity. Takeda agreed to structure the March 2010 pact so as to maintain the illusion that the first wave generics remained entitled to a 180-day exclusivity due to paragraph IV certifications to an Orange Book listing for the drug product ACTOS.

268. Structuring the March 2010 pact to maintain the false 180-day ACTOS exclusivity would have significant, anticompetitive consequences. Generic manufacturers know that they will reap and maintain a significant first-mover advantage if they are the first or part of the first wave of generics to enter the market. The first wave entrants capture and retain a disproportionate share of the generics market even once other generics enter the market. And first-wave generics are able to charge higher prices for and earn greater profits from their generic products prior to the entry of later generics. By limiting competition during the first six months, the first wave generics can charge higher prices.

269. *Third*, the practical result of the March 2010 pact was that Takeda would not be competing against the first wave generics with its own, independent (of Mylan, Actavis, Ranbaxy or Teva) authorized generic. Given the blockbuster size of the ACTOS and ACTO*plus* markets, absent agreements to do otherwise, a rational brand company in the

position of Takeda would, upon generic entry, launch its own authorized generic on market rate terms, and this launch would add to the generics on the market. Under the March 2010 pact, however, the practical result was that Takeda was limiting its authorized generic options to distributorships through the first wave generics and Teva, thus eliminating the launch of its own, independent authorized generic.

270. *Fourth* (and for Mylan), Takeda agreed that, in the event that any other generic ACTO*plus* met entered the market before the time specified for Mylan to enter, the agreed-upon entry date for Mylan would be moved up correspondingly. As with the other coordination clauses, the purpose and effect of the ACTO*plus* coordination clauses was to deter any other generic drug manufacturer from entering before Mylan's scheduled entry date – it sought to lock in Mylan's 180-day exclusivity for ACTO*plus* met.

271. *Fifth* (and for Mylan), Takeda agreed that the terms on which Takeda and Mylan agreed to settle the ACTOS lawsuit were contingent on the terms on which those parties agreed to settle the ACTO*plus* met lawsuit, and *vice versa*. The payments and provisions were designed to (and eventually would) deter Teva from undermining the March 2010 pact with respect to ACTOS. In exchange for the anticompetitive coordination clauses that Mylan received with respect to both lawsuits, including those successfully designed to deter Teva from undermining the ACTOS anticompetitive scheme, Mylan agreed to delay entry of generic ACTO*plus* met.

272. *Sixth* (and for Ranbaxy), Takeda agreed to give Ranbaxy two, higher-than-market, side deals. For the ACTOS deal, Takeda gave Ranbaxy a distribution right to enter with an authorized generic ACTOS under distribution terms that provided Ranbaxy with net revenue far in excess of fair market terms. Authorized generic distributorship agreements

carry a market rate distribution rate that, accordingly to some Ranbaxy information, typically permits the distributor to retain about 10% of the net revenues. In this deal, however, Ranbaxy was permitted to retain about 25%, or more than two and half times more the rate treated as customary.

273. For the ACTO*plus* met deal, Ranbaxy had not filed an ANDA seeking FDA approval to market ACTO*plus* met and had not made any certifications that Takeda's patents on ACTO*plus* met were invalid or would not be infringed by a generic version of ACTO*plus* met. But in order to induce Ranbaxy to delay entry with its generic ACTOS, Takeda gave Ranbaxy a distribution right for ACTO*plus* met that was of substantial value to Ranbaxy and was compensation that it could not have been obtained even if it had won the ACTOS patent litigation.

274. *Seventh* (and for Actavis), Takeda gave Actavis a higher-than-market deal. Actavis had not filed an ANDA seeking FDA approval to market ACTO*plus* met and had not made any certifications that Takeda's patents on ACTO*plus* met were invalid or would not be infringed by a generic version of ACTO*plus* met. But in order to induce Actavis to delay entry with its generic ACTOS, Takeda gave Actavis a distribution right for ACTO*plus* met that was of substantial value to Actavis and was compensation that it could not have been obtained even if it had won the ACTOS patent litigation.

275. *Eighth*, under the March 2010 pact, Takeda purportedly gave "licenses" to Mylan, Ranbaxy, and Actavis to market ACTOS, but in reality these were not "licenses" at all. Since the agreements actually contained commitments by each of Mylan, Ranbaxy, and Actavis *to not market generics* for an extended period of time, then for that period of time the provisions cannot be characterized as "licenses" and are instead better characterized as anti-licenses –

agreements that prohibit, not license, market entry. And while ostensibly the agreements provided a "licensed" entry date after the delayed entry period lapsed, a "license" (in the sense of a consensually derived business arrangement) was neither needed nor appropriate to settle the patent challenge. Instead, in substance, these defendants were simply reaching a covenant not to sue. The defendants' use of the term "license" was crafted in the agreements as a pretext to hide the reality that the substance of the arrangements was *delay* of entry (not permission of entry), with a barren covenant not to sue thereafter.

276. The structure of these "licenses" through the use of the coordination clauses was such that they *dis*incentivized the primary competition (Teva) to come to market at all. This disincentive took the following form: Teva knew that if it litigated, won, and entered early, the coordination clauses would mean that the other generic manufacturers would share in the fruits of Teva's win. Absent the coordination clauses, the other generics would be bound by their agreed entry dates and would not share in Teva's earlier entry.

277. The "licenses" and related scheme served as a mask for collusive conduct. If the March 2010 pact had not unlawfully enticed Takeda and its would-be generic competitors to work together, consumers would have been able to purchase generic options earlier, *and* those purchases all would have been made at lower prices than they did once those generics came to market.

278. All of these benefits had substantial value to Mylan, Ranbaxy, and Actavis, and are compensation that they could not have otherwise obtained even if they had litigated and won the various patent cases. The arrangements caused Mylan, Ranbaxy, and Actavis to stay out of the markets for ACTOS and ACTO*plus* met longer than they otherwise would have.

279. In the absence of the March 2010 pact (*i.e.*, without the coordination clauses inducing Teva to drop its section viii approach, without structuring the deal to maintain a shared 180-day exclusivity that would vanish upon a decision in the Teva case, and without distributorships at higher than fair market terms), reasonable, law-abiding generic companies in the position of Mylan, Ranbaxy, and Actavis each would have demanded, and received, an earlier agreed entry date, *i.e.*, a date markedly earlier than August 17, 2012 and closer to the end of January 2011. Takeda made these promises to Mylan, Ranbaxy, and Actavis in exchange for their agreeing to delay entry with their generic ACTOS and ACTO*plus* met products.

N. Teva moves to add a counterclaim pursuant to 21 U.S.C. § 355(j)(5)(C)(ii) against Takeda, but soon thereafter shifts to settlement mode.

280. With the execution of the March 2010 pact (and the consequent prolonged bottlenecks that also delayed entry by later-filing generic drug manufacturers), Takeda and its generic co-conspirators -- Mylan, Ranbaxy, and Actavis -- had restricted several of the competitive pressures that would have brought lower prices to drug purchasers before the dates specified in the March 2010 pact. But one significant threat remained, Teva.

281. We detail the chronology below, but first an observation: It is not the case that Teva continued vigorously litigating after the settlements were announced. To the contrary. One week after the settlements comprising the March 2010 pact were announced, Teva sought to amend its counterclaim. But less than two weeks later, the case was effectively stayed. A series of letters followed, with the parties continually saying that they were talking, that they thought they could resolve the case, and asking the court to please maintain the current case status (*i.e.*, not take any action).

282. On March 30, 2010, Teva filed a motion to amend its answer to add a counterclaim against Takeda based on Takeda's improper submission of patent information for the '584 and '404 patents describing the patents as drug product patents claiming ACTOS. As Teva stated in its proposed Amended Answer, Affirmative Defenses and Counterclaim:

> As a direct and proximate cause of Takeda's submission of false, misleading, and/or incorrect patent information to FDA . . . Teva is likely to suffer significant harm in the form of a substantial delay to the approval of Teva's Actos® ANDA. If Teva is required to file a Paragraph IV certification due to the incorrect listings of the '584 and the '404 patents in the Orange Book, Takeda might file a new lawsuit triggering a 30-month stay of approval of Teva's Actos® ANDA. In addition, whether or not Takeda files such a lawsuit, Teva's ANDA could not be approved until after the expiration of any 180-day exclusivity period to which the first-filer(s) of ANDA(s) for generic versions of Actos® may be entitled. Either way, final approval of Teva's Actos® ANDA likely will be delayed substantially beyond the January 2011 date (the expiration of the '777 patent) on which Teva's ANDA otherwise likely would be approved.

283. Teva sought an order pursuant to 21 U.S.C. § 355(j)(5)(C)(ii) requiring Takeda "to correct or delete the patent information Takeda submitted to FDA in reference to NDA 21-073 concerning the drug product claims in the '584 and '404 Patent[s] by submitting information to FDA clarifying that the drug product claims in those patents do not claim the drug product approved by NDA 21-073 and that those drug product claims do not form a basis upon which Takeda could reasonably assert a claim of patent infringement against an ANDA applicant for a generic version of Actos®." Had Teva succeeded on its counterclaim, Teva would not have been subject to the 180-day bottleneck that Takeda and Mylan, Ranbaxy, and Actavis constructed and extended with their March 2010 pact, and Teva could have entered the

market with generic ACTOS as early as January 17, 2011. And given the firm trial date of June 7, 2010, Teva could achieve a ruling well ahead of its planned late January 2011 launch.[68]

284. While Teva had shown by the March 30, 2010 filing that it was intent to seek to pursue the section viii route to the launch of an ACTOS generic, that position quickly changed. On several dates in March the first wave generics announced their settlements. By the end of March 2010, Takeda also entered into settlement agreements with Alphapharm and Torrent, and the court entered orders of dismissal in the cases against these five defendants by April 2, 2010.[69]

285. On March 22, 2010, Teva informed the Court that the FDA had issued its decision on the outstanding Citizen Petition filed by Sandoz, Inc. regarding generic pioglitazone and generic pioglitazone/metformin filings. On March 30, 2010, Teva filed a motion for leave to supplement its pleadings "to add a newly mature counterclaim."

286. On April 1, 2010, Takeda and the remaining defendants, Teva and Sandoz, requested that the Court amend the pretrial deadlines, including the extension of the due dates for motions *in limine* and the joint pretrial order to May 3, 2010 and May 6, 2010, respectively,

[68] At the time, Teva had the benefit of a firm trial date. Back in February of 2007, the court had entered an order lifting a stay of litigation regarding Takeda's claims of infringement of its pioglitazone combination-use patents, and set a trial date of April 26, 2010. Although new cases had been added, the court retained the same trial date of April 26, 2010 for all cases. On December 7, 2009, the Court reset the trial date from April 26, 2010 to April 5, 2010. On December 22, 2009, the Court reset the trial date to June 7, 2010 and set the final pretrial conference for April 16, 2010. Despite other scheduling changes, the court kept the June 7, 2010 trial date in place until a status conference with Takeda and Teva in mid-April, 2010.

[69] Order for Dismissal, Docket Entry 162, Civil Action No. 03-cv-08250-DLC (S.D.N.Y. Apr. 1, 2010) (Ranbaxy); Amended Order for Dismissal, Docket Entry 162, Civil Action No. 03-cv-08250-DLC (S.D.N.Y. Apr. 2, 2010) (Ranbaxy); Order for Dismissal, Docket Entry 204, Civil Action No. 03-cv-08253-DLC (S.D.N.Y. Apr. 2, 2010) (Mylan); Order for Dismissal, Docket Entry 63, Civil Action No. 03-cv-08254-DLC (S.D.N.Y. Apr. 2, 2010) (Watson); Order for Dismissal, Docket Entry 158, Civil Action No. 04-cv-01966-DLC (S.D.N.Y. Apr. 2, 2010) (Alphapharm); Order for Dismissal, Docket Entry 42, Civil Action No. 09-cv-06051-DLC (S.D.N.Y. Apr. 2, 2010).

and noted that "[t]he schedule requested herein is based on the currently scheduled June 7, 2010, trial date." The Court granted the parties' request.

287. On April 14, 2010, the Court held a telephone conference with counsel for "both parties," Takeda and Teva. (Presumably, Takeda and Sandoz had reached a settlement by this time, although the cases involving Sandoz were not dismissed until April 27 and the settlement was not announced until April 28). After the telephone conference, the court entered an order providing that "[f]or the reasons stated on the record, it is hereby ORDERED that the trial in this matter scheduled for June 7, 2010 is adjourned sine die . . . . "

288. On August 31, 2010, Takeda and Teva provided a status update to the court, stating "the parties have begun exploring settlement . . . ."

289. In summary, the court stayed Teva's motion to add its counterclaim on April 14, and in effect stayed the case in order to allow the FDA to make further decisions about the use codes for the '584 and '404 patents, and by August Takeda and Teva had already begun discussing settlement of the litigation.

290. By December 21, 2010, Takeda and Teva had reached a settlement agreement,[70] and the Court dismissed the case on December 22, 2010.[71]

291. In those settlement discussions, Takeda had set the stage to prolong its ACTOS franchise, as it had both created disincentives for Teva to continue its patent and Orange Book listing challenges, and was also willing to pay Teva additional sums in order to get it to a generic delay deal.

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[70] Takeda press release, Takeda Completes Settlements With All Defendants in U.S. Patent Litigation Involving ACTOS® (pioglitazone HCl), ACTO*plus* met® (pioglitazone HCl and metformin HCl) and duetact® (pioglitazone HCl and glimepiride) (Dec. 21, 2010).

[71] Order for Dismissal, Docket Entry 75, Civil Action 09-cv-04665-DLC (S.D.N.Y. Dec. 22, 2010).

292. The disincentives included the coordination clauses that Takeda and its other generic drug manufacturer co-conspirators had incorporated in the March 2010 pact for both ACTOS and ACTO*plus* met. The coordination clauses provided a hypothetical that, in the event that any other manufacturer succeeded in entering the market with a generic ACTOS product before August 17, 2012, the agreed-upon entry date for Mylan, Ranbaxy, and Actavis would be accelerated to the earlier date. The coordination clauses thus ensured that no other generic drug manufacturer, no matter how much time and resources it spent in its litigation against Takeda, and no matter how successful the generic drug manufacturer was in the litigation, could enter the market before Mylan, Ranbaxy, and Actavis. The May 2010 pact between Takeda and Mylan with respect to ACTO*plus* met had a similar coordination clause.

293. The purpose and effect of the coordination clauses was to dramatically reduce Teva's incentive to try to enter the market before Mylan, Ranbaxy, and Actavis. Absent the coordination clauses, Teva was likely to enter the market with generic ACTOS by the end of January, 2011, and thereby enjoy first mover advantages with less competition from others. By eliminating this possibility, the coordination clauses reduced Teva's incentive to continue litigating in order to gain entry before Mylan, Ranbaxy, and Actavis.

294. While keeping most of the terms in their March 2010 pact confidential, Mylan, Ranbaxy, and Actavis agreed that Takeda could advise Teva of the existence of the coordination clauses.

O. Takeda and Teva execute the December 2010 pact to delay generic ACTOS and ACTO*plus* met.

295. On December 22, 2010, Takeda and Teva entered into an agreement pursuant to which Teva agreed to: (i) drop its challenges to Takeda's patents with respect to both ACTOS and ACTO*plus* met; (ii) drop its counterclaim asserting that Takeda had submitted false and

misleading patent information as to the '584 and '404 patents; and (iii) stay out of the market with generic ACTOS until August 17, 2012, and stay out of the market with generic ACTO*plus* met until the date on which Mylan entered the market (the "December 2010 pact").

296. What Takeda had contemplated in the March 2010 pact came to fruition: Takeda gave Teva, among other things, the opportunity to participate in the first unlawful Actos oligopoly by giving Teva the right to sell an ACTOS authorized generic during the first six months the first wave generics. In exchange, Teva joined the conspiracy and promised to delay until well after the expiration of the '777 Patent.

297. As the *quid pro quo* for Teva's agreement to significantly delay competition, Takeda gave Teva a package that, as a practical matter, (i) folded Teva into the position of the first wave generics by permitting Teva to enter the ACTOS market at the same time as the first wave generics despite the fact that the first wave generics would have the falsely created 180-day exclusivity, and (ii) permitted Teva to enter the ACTOplus market at the same time as Mylan despite Mylan's 180-day exclusivity for that drug. In economic terms, Takeda gave Teva the ability to enter two oligopolies: first, the falsely created 180-day exclusivity for ACTOS (where only the first wave generics and Teva could participate with generic ACTOS), and second, the 180-day exclusivity for ACTOplus (where only Mylan and Teva could participate with generic ACTOplus).

298. The December 2010 pact took at least the following forms.

299. *First*, Takeda gave Teva an authorized generic distributorship for ACTOS in which Teva could enter the market at the same time as the first wave generics, i.e., August 17, 2012. Takeda's ability to do so had been expressly reserved in the March 2010 pact as a means by which to entice Teva to drop its section viii efforts and join the delay of generic ACTOS.

300. The oddity of having the Teva (which already had tentative approval for its own ACTOS generic) selling instead the authorized generic of Takeda was necessitated by the structure of seeking to preserve the first wave generics' falsely created 180-day exclusivity. Because the March 2010 pact sought to preserve the falsely created 180-day exclusivity for ACTOS, Teva would not be able to get final FDA approval for its *own ANDA* generic in order to launch its own product on August 17, 2012; as a result, in order to get Teva onto the market with the first wave generics, but at the same time maintain the oligopoly and keep all others out, Takeda and Teva had the unusual agreement that Teva would sell Takeda's ACTOS authorized generic for six months, with Teva thereafter being able to sell its own product afterwards.

301. The terms of Takeda-Teva ACTOS authorized generic deal were structured to have a *de facto* payment from Takeda to Teva. Under the deal, Teva was only required to pay Takeda a royalty of 75% of its net profits, but market rates for an authorized distributorship in these circumstances would require a much higher rate, at about 90%. In effect, Teva was allowed to retain 25% of it profits, rather than about 10%, or about 2½ times a market rate compensation.

302. *Second*, the Takeda agreed that, with the exception of the "licenses" to which it had already agreed with Mylan, Ranbaxy, and Actavis, Takeda would not grant any other generic drug manufacturer a release of patent liability for entering the market with generic ACTOS earlier than 180 days after Teva entered the market. This preserved the ability of Teva and the first wave generics to enjoy the benefits of the two oligopolies.

303. *Third*, Takeda agreed that, in the event any other generic ACTOS entered the market before the time specified for Teva to enter the market, the agreed-upon entry date for

Teva would be coordinated with the entry date for the first wave generics. The purpose and effect of this coordination clause was to deter any other generic drug manufacturer from entering before Teva's scheduled entry date.

304. *Fourth*, Takeda gave Teva an authorized generic distributorship for ACTOplus in which Teva could enter the market at the same time as Mylan, i.e., December of 2012 (or August under certain circumstan7yces that did come to pass). Takeda's ability to do so had similarly been expressly reserved in the March 2010 pact with Mylan as a means by which to entice Teva to drop its section viii efforts and join the delay of generic ACTOplus.

305. As with the other authorized generic deal, the Takeda-Teva ACTOplus authorized generic deal was structured to have a *de facto* payment to Teva, at the same below market rate of 75%.

306. *Fifth*, Takeda agreed that, with the exception of the "licenses" already granted to Mylan, Takeda would not grant any other generic drug manufacturer a release from patent liability for entry into the market with generic ACTO*plus* met until 180 days after Teva entered the market.

307. *Sixth*, Takeda agreed that, in the event any other generic ACTO*plus* met entered the market before the time specified for Teva to enter the market, the agreed-upon entry date for Teva would be coordinated correspondingly. The purpose and effect of this coordination clause was to deter any other generic drug manufacturer from entering before Teva's scheduled entry date.

308. All of these benefits had substantial value to Teva, and are compensation that it could not have obtained even if it had litigated and won the patent case. The combination of the disincentives created by the March 2010 pact, coupled with the promises made by Takeda

in the December 2010 pact, caused Teva to drop its section viii statement approach to getting on to the ACTOS market by the end of January of 2011, and stay out of the ACTOS and ACTO*plus* met markets longer than it otherwise would have done.

P. The other generics fall in line.

309. Sandoz and Aurobindo had notified Takeda that they had filed ANDAs for generic ACTO*plus* met that contained a paragraph IV certification with respect to the '584 Met Combo Patent and the ACTO*plus* met Method-of-Use Patents. In each case, Takeda filed a patent infringement suit alleging the generic ACTO*plus* met product in question would directly infringe the '584 patent and indirectly infringe certain of the ACTO*plus* met Method-of-Use patents. Takeda filed these patent infringement cases against the potential generic drug manufacturer competitors without regard to the merits of the cases. Simply by filing the lawsuits, Takeda obtained automatic exclusion of these ANDA filers from the market for thirty months.

310. In light of the prolonged bottleneck created by the March 2010 and December 2010 pacts, all of these subsequent ANDA filers entered into joint stipulations dismissing their patent cases with Takeda. Each of these potential competitors agreed to delay entry into the market until 180 days after Mylan and others entered. Absent the prolonged bottlenecks created by the unlawful pacts, many or most of these later ANDA filers would have entered the market much sooner than they did.

Q. The 2011 through 2014 overt acts in furtherance of the March and December 2010 pacts.

311. From late January of 2011 (when they otherwise could have entered the ACTOS and ACTO*plus* met markets) until late August of 2012, each of Mylan, Actavis, Ranbaxy and Teva abided their agreements with Takeda – they did not launch generic products into those

markets, and undertook whatever activities were required (with, for example, the FDA) so as to make sure they kept the promise to Takeda to stay out until late August of 2012, and that they did not sell or relinquish the 180-day exclusivity. Meanwhile, Takeda kept its promise and did not grant any licenses to other generic companies or AG distributors that would interfere with the benefits of the falsely created exclusivity period for ACTOS generics.

312. In or about the summer of 2012, Takeda worked closely with two of its co-conspirators – Teva and Ranbaxy – in order to implement the sweetheart authorized generic distributorships Takeda had granted them for ACTOS. In or about late August of 2012, Takeda and Teva, and also Takeda and Ranbaxy, launched authorized generics of ACTOS. Neither Teva nor Ranbaxy launched their own, ANDA-approved generic at this time. Takeda also kept its commitment not to launch a (market rate) authorized generic through an AG distributor.

313. For at least two years, and certainly into 2014, Takeda continued to pay both Teva and Ranbaxy through the sweetheart, authorized distributorships. The absence of any other authorized generic allowed Teva to maintain the price of its generic product at artificially inflated prices. The distributorship was so valuable to Teva that Teva did not press for approval of its own ANDA-approved ACTOS generic for many, many months.

314. In or about the summer of 2012, Takeda also worked closely with Teva in order to implement the below market rate authorized generic distributorship Takeda had granted Teva for ACTO*plus* met. In or about late August of 2012, Takeda and Teva launched an authorized generic of ACTO*plus* met. Teva did not launch its own, ANDA-approved generic at this time. Takeda also kept its commitment not to launch an independent (market rate) authorized generic of ACTO*plus* met.

315. For at least two years, and certainly into 2014, Takeda continued to pay Teva through the lower than market rate royalty authorized distributorships. The absence of any other authorized generic allowed Teva to maintain the price of its generic product at artificially inflated prices. The distributorship was so valuable to Teva that Teva did not press for approval of its own ANDA-approved generic for many, many months.

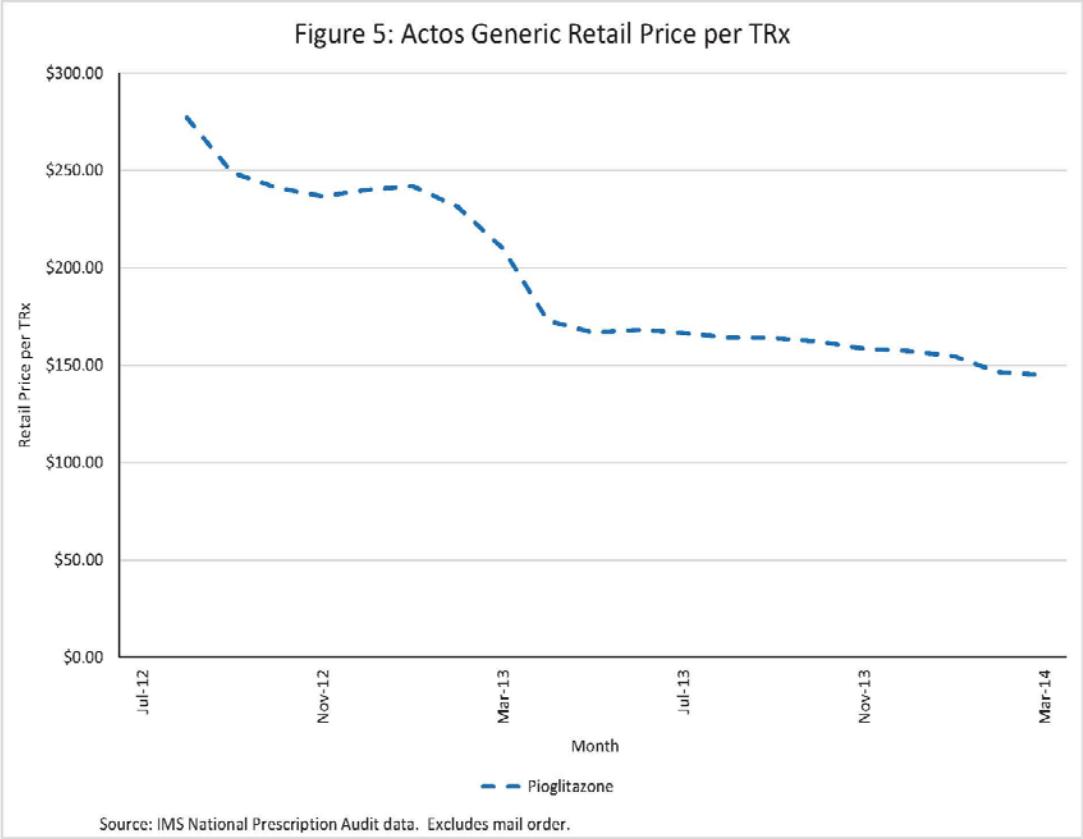
R. The impacts on competition from the wrongful Orange Book listings and the March and December 2010 pacts.

316. Takeda's wrongful Orange Book listings of the '584 and '404 patents as claiming the ACTOS product, and the subsequent March and December 2010 pacts, were intended to restrict, and did restrict, competition in the markets for ACTOS and ACTO*plus* met in multiple ways.

317. *First*, the defendants' acts restricted competition by creating and maintaining a false 180-day exclusivity for ACTOS. This exclusivity existed solely because Takeda had wrongfully listed the '584 Met Combo Patent and '404 Insulin Combo Patent as covering the drug product ACTOS in the Orange Book. The March 2010 pact perpetuated that exclusivity, and through coordinated entry agreements amongst competitors successfully contributed to persuading Teva to drop its section viii efforts (which otherwise would have destroyed to ACTOS faux 180-day exclusivity). The December 2010 pact solidified the creation of this false oligopoly by having Teva drop its section viii efforts so long as it (and no further others, including Takeda) got to participate in the ACTOS generic 180-day exclusivity.

318. By creating and maintaining this false oligopoly, competition was stifled and prices kept at supracompetitive levels. Figure 5 below shows a conservative pre-discovery estimate of the prices charged for generic ACTOS, including the impact on price of the entry of later generics. For example, during the first six months (when only the co-conspirators Teva,

Actavis, Ranbaxy and Mylan were on the market), the reported price point is about $245 per prescription, but after expiration of that six-month exclusivity period, the price range drops to about $150 to $165 per prescription. (Of course, the dates for these prices would be shifted earlier – to the left, if you will – in the event of earlier generic entry).

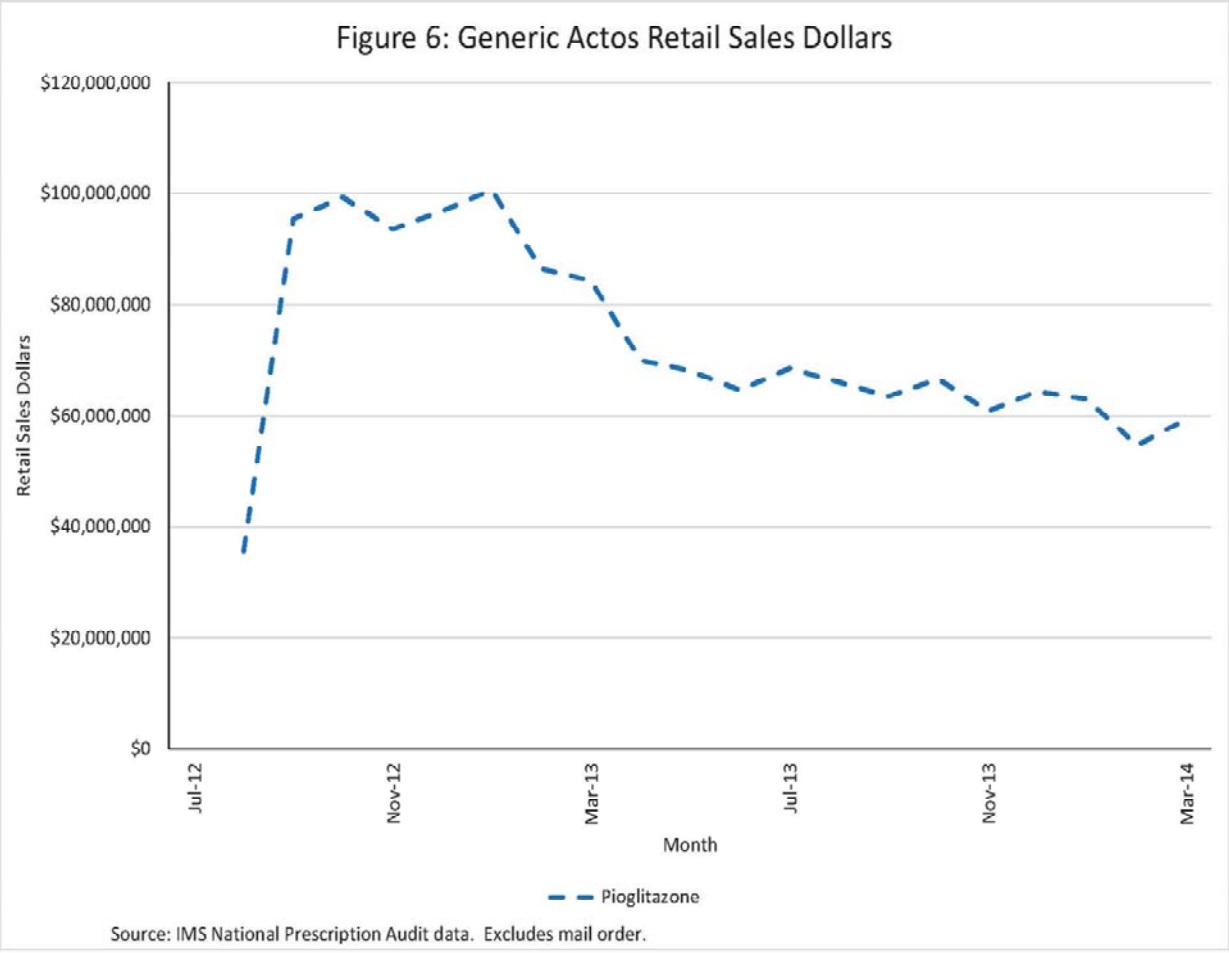


319. In other words, a supracompetitive price existed in the market for ACTOS during the first six months of actual generic entry, and then dropped to competitive rates following six months. But competitive conditions (in which there was no need for paragraph IV certifications to a product claim for ACTOS, nor any 180-day exclusivity) would have yielded competitive prices of the type seen after the six months lapsed.

320. As a result of the defendants' wrongful acts, the first wave generics in fact charged supracompetitive prices during a period of time (the first six months) to which they

would not have been entitled to 180-day exclusivity if (i) Takeda had not made the false Orange Book listing in the first place, or (ii) the parties to the pact had not succeeded in getting Teva to drop its § 355(j)(5)(C)(ii) counterclaim. Prices charged by the first wave generics were over 50% higher during the first six months than during later, competitive conditions.

321. Figure 6 below shows a pre-discovery estimation of reported generic sales. During the first six months, the first-wave generics had combined reported sales in the $90 to $100 million per month range, but after expiration of that six-month exclusivity period, combined reported sales dropped to the $60 to $80 million per month range. (Again, the dates for these sales would be shifted earlier – to the left – in the event of earlier generic entry).



322. As a result of the structure of the defendants' acts, the first wave generics and Teva earned sales of at least $350 million more than they otherwise would have if (i) Takeda had not made the false Orange Book listing in the first place, or (ii) the parties to the pacts had not succeeded in getting Teva to drop its § 355(j)(5)(C)(ii) counterclaim (and thus keep their 180-day exclusivities).

323. If Takeda had not included the coordination clauses for Mylan, Ranbaxy, and Actavis, each of those generic companies would not have gained the over $350 million in sales from the anticompetitive pact; in the absence of such a deal, reasonable, law-abiding generic companies in the position of Mylan, Ranbaxy, and Actavis would have insisted upon agreed-entry dates markedly earlier, and close to, the end of January 2011.

324. *Second*, the arrangement restricted competition by prolonging the bottleneck presented by the false 180-day exclusivity held by the first wave generics for ACTOS. Because each of the first wave generics had filed their ANDAs for ACTOS before enactment of the 2003 MMA amendments, under the law before the amendments the first generic manufacturer(s) to file an ANDA with a paragraph IV certification could not forfeit the 180-day exclusivity by failing to market the drug. Therefore, the first generic drug manufacturer applicant could agree with the branded drug manufacturer to delay marketing the generic, while still safely retaining the 180-day exclusivity. By thus "parking" its 180-day exclusivity, the first filer could create a "bottleneck" that precluded *all* generic drug manufacturers from entering the market until 180 days after the first filer entered.

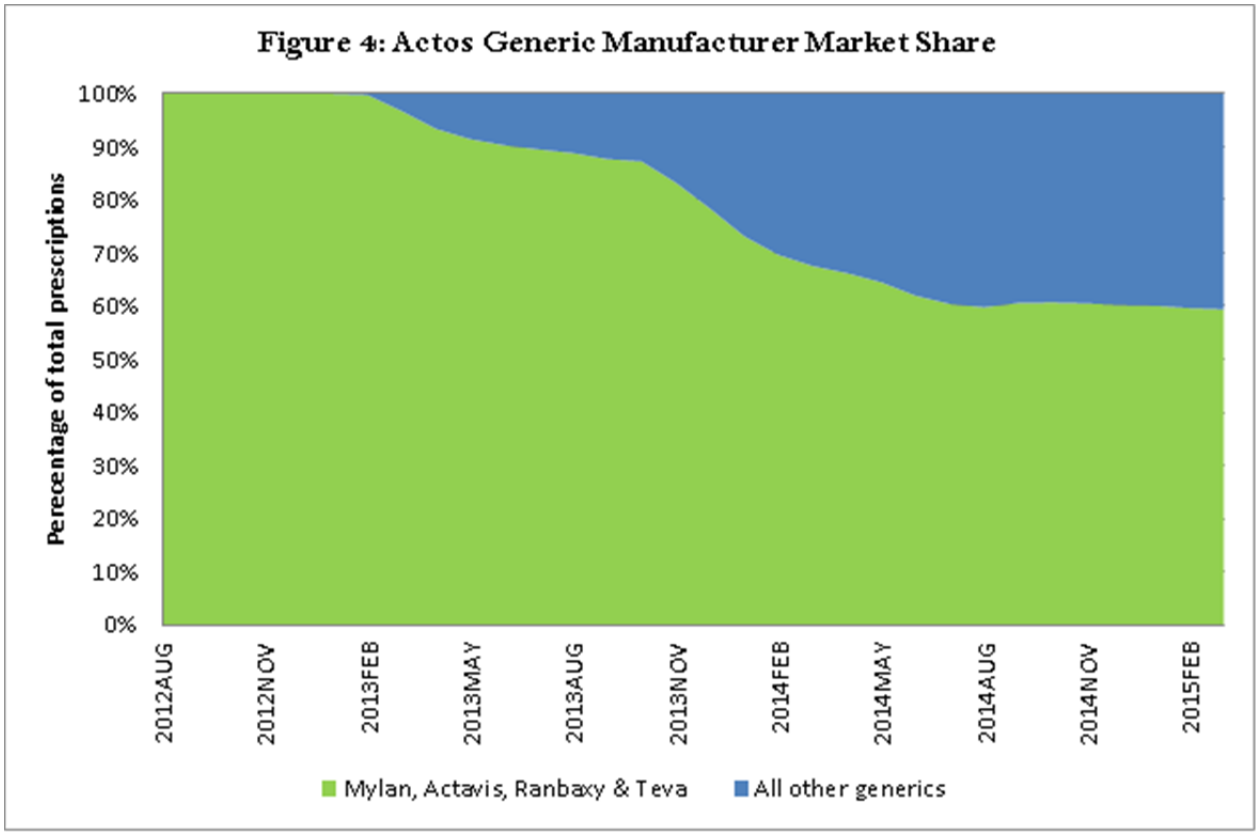
325. The intended effect of Takeda's March and December pacts was to delay entry into the market by them and all subsequent ANDA filers. Other generic drug manufacturer competitors had notified Takeda that they had filed ANDAs for generics of ACTOS that

contained a paragraph IV certification as to the '584 and '404 patents product claims. In each case, Takeda filed a patent infringement suit against the generic manufacturer alleging that the manufacturer's generic ACTOS product would infringe the '584 and '404 patents. Takeda filed the patent infringement cases against these potential generic drug manufacturer competitors without regard to the merits of the cases. Simply by filing the cases, Takeda obtained automatic exclusion of these ANDA filers from the market for thirty months.

326. In light of the prolonged bottleneck created by the defendants' acts, the later generic filers each were, as a practical economic matter, required to fall in line with the protracted, delayed entry date for ACTOS generics.

327. The benefit to the first wave generics and Teva in beating the other generics to the market through the false oligopoly can be shown from the persistence of the benefit from being the first generics to the market.

328. Figure 4 below shows a pre-discovery estimation of reported share of the generic sub-market for ACTOS held by the first wave generics and Teva. Not only did they get all generic sales during the first six months, even after other generics gained the right to market entry after six months they gained relatively little market share for many months.

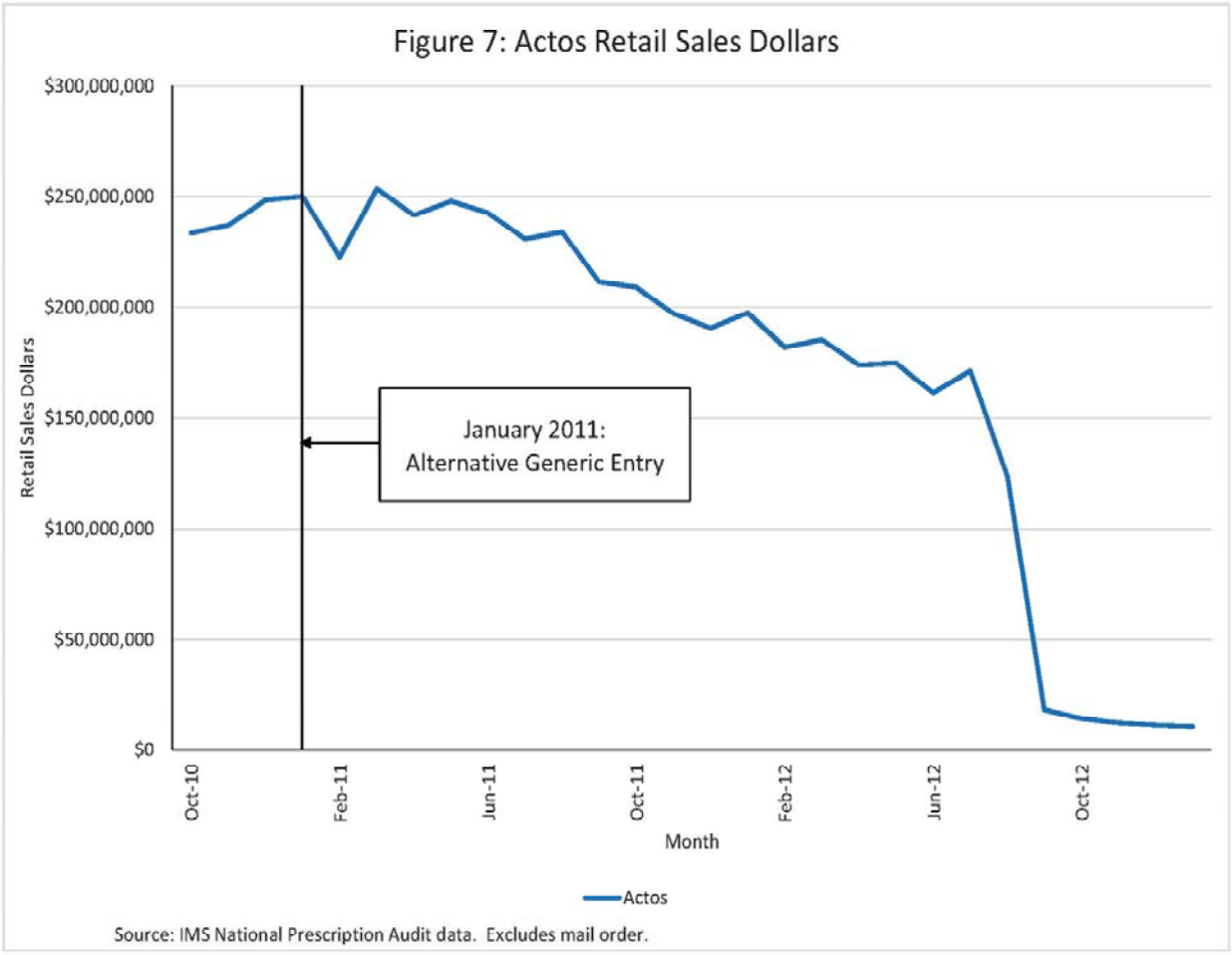


329. The pre-discovery data enables a reasonable estimation of the value to the first wave generics and Teva from the anticompetitive consequences of the March and December pacts. Pre-discovery data shows that the generic ACTOS submarket shares for these companies was Teva about 33%, Mylan 33%, Ranbaxy 24% and Actavis 10% (which launched later in the oligopoly period). Based on the excess sales estimation of $350 million, the excess realized sales for each of these companies was Teva about $115 million, Mylan about $155 million, Ranbaxy about $84 million, and Actavis about $35 million. Even after payment of "royalties" to Takeda, each of them was receiving tens of millions of dollars more than they would have received had they been participating in a competitive market.

330. In March of 2010, trial was three months away. Takeda would certainly incur more litigation fees and expenses, but most of the litigation was in the rear view mirror.

Takeda's projected reasonable litigation fees and expenses likely would not exceed another $5 to $10 million, an amount far less than the estimate of the value it granted to the first wave generics and Teva in assuring their participation in two periods of supracompetitively priced oligopolies. The March and December 2010 pacts cannot be justified based on the notion of Takeda's avoided litigation costs.

331. *Third*, generics were delayed from late January 2011 until late August of 2012, during which time, as the pre-discovery estimation in Figure 7 below shows, ACTOS monthly sales were over $200 million.



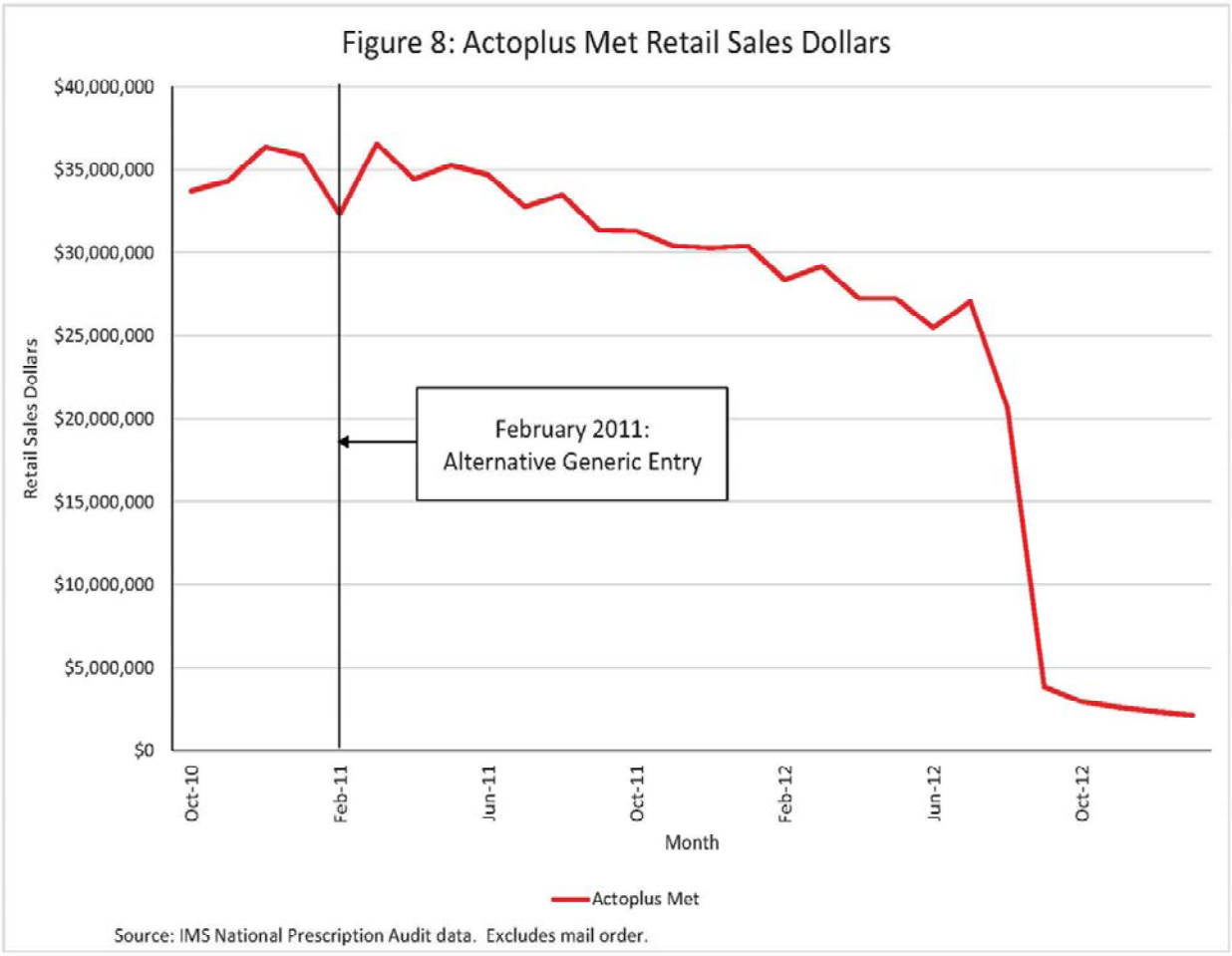
332. This delay allowed Takeda to charge supracompetitive prices for far longer than it may have been lawfully entitled. In effect, the wrongful Orange book listings, along with the March and December 2010 pacts, protected Takeda from generic competition for a period of time during which retails sales totaled about $3.6 billion.

333. The agreements' plan to protect high sales for a few generics during the first six months of entry worked. During this period, only the conspiring generics were able to get into the ACTOS market and they shared sales of about a $100 million per month; upon entry of the later generics, the market size would drop to about $60 million per month. And the agreement's plan to keep prices relatively high for the first six months of exclusivity also worked; while in the first six months the average retail price was in the $240 to $250 per prescription range, post-exclusivity the average retail price dropped to about $165 per prescription or lower.

334. A competitive market for ACTOS would have yielded about $60 million a month shared amongst many competitors; it would not have been the $200 million a month Takeda enjoyed by itself for 18 months, nor the $100 million a month the co-conspiring oligopoly of generics enjoyed for the first six months of (unlawfully produced) exclusivity.[72]

335. *Fourth*, ACTO*plus* met generics were delayed from late January until late August of 2012, during which, as the pre-discovery estimation in Figure 8 below depicts, monthly sales were about $30 million.

[72] These numbers are, of course, pre-discovery and are based only on publicly available information. They will be refined, of course, during discovery.



336. This delay allowed Takeda to charge supracompetitive prices for far longer than it may have been lawfully entitled. In effect, the agreement protected Takeda from generic competition during which retails sales totaled about $540 million.

337. *Fifth*, the March and December 2010 pacts permitting only first wave generics and Teva on the market for ACTO*plus* met for the first six months added some value to the deal from their point of view. During this period, only Mylan, Teva and Ranbaxy (three of the conspiring generics) were able to get into the ACTO*plus* met market, and they shared sales of about a $17 million per month market; upon the entry of other generics, the market size would drop to about $14 million per month. The agreement's plan to keep prices relatively high

period the first six months of exclusivity also worked; while in the first six months the average retail price was in the $300 per prescription range, post-exclusivity the average retail price dropped to about $285 per prescription or lower.

338. By creating an ACTOS exclusivity where none should exist, by maintaining that exclusivity through agreements between competitors, and encouraging delayed entry through below market rate authorized generic deals, the March and December 2010 pacts did far more than just grant a purported "compromise" date for entry.

339. The coordination provisions worked their intended result – providing incentive to Teva to drop the section viii effort. The impact of the coordination provisions must be evaluated in the context of the false Orange Book listings, paragraph IV certifications and false 180-day exclusivity that exists in this case. The practical effect of the coordination clauses was not to increase competition in the event that the other generics entered the market earlier than contemplated by the agreement, but rather to accomplish exactly what happened here – to have Teva discontinue its section viii efforts. The trigger for acceleration was here highly unlikely, as in fact history demonstrated.

340. Nor would it be correct to state that, in the absence of a triggering event, the effect of the coordination clauses would be neutral. In fact and in accordance with applied microeconomics, the clauses had the *in terrorem* effect they were intended to have (even in the absence of being triggered), by working to uncut the incentives of Teva to pursue its section viii ANDA approval.

341. It is true that if the clauses were not triggered, the delayed entry date of August 17, 2012 remained in effect, but that was the anticompetitive problem – an entry date about 20 months later than even Teva had previously predicted for its ACTOS generic launch. And

while if not triggered the clauses retained the 180-days of generic market exclusivity, that too was just the problem – the clauses in the pacts aided maintaining an exclusivity that should not have existed in the first place.

342. The impact of the coordination clauses is shown by Teva's reaction to them. In the wake of the learning about the March 2010, Teva soon discontinued its litigation efforts and turned to settlement. And the impact of the coordination clauses is shown also by the reaction of the other generics. All of the later generics fell in line and accepted the delayed entry of ACTOS and ACTOplus generics.

343. The March and December 2010 pacts affixed an entry date for ACTOS generics that was 20 months after the expiry of the '777 patent, and barred even ACTOS generics that had a carved-out combination use with metformin and insulin.

344. The grants of authorized generic distributorships to the first wave generics and Teva for ACTOS or ACTO*plus* met had no pro-competitive benefit. Takeda was in a position to grant an authorized generic distributorship to any willing and able distributor; the choice of giving such a distributorship to *these* generics did not add any material benefit to the market than would be achieved by its giving the distributorship to an independent distributor. Competition from an authorized generic otherwise would have existed, and so the grant to these particular generics did not add competition. Instead, the only impact was anticompetitive in that the grants provided incentives to delay *bona fide* generic entry. And here the grant of distribution rights with below market "royalty" rates, and as part of a structured deal intended to delay generic entry, makes them part and parcel of the anticompetitive scheme.

345. Nor is there any pro-competitive aspect to the fact that the March and December pacts permitted Takeda to license an authorized generic after the expiry of the two 180-day

periods. It always had that right, and the damage was done by its agreement to tightly limit the authorized distributorships within the co-conspirators' oligopoly.

346. The grant of the benefits in the March and December 2010 pacts was a substantial contributing factor to the first wave generics' and Teva's decisions to agree to a late entry date for the entry of ACTOS and ACTO*plus* met generics.

347. The March and December 2010 pacts ran roughshod over the Hatch Waxman scheme. The agreements were the worst of all worlds.[73]

VI. ANTICOMPETITIVE EFFECTS OF THE SCHEME AND AGREEMENTS

348. The defendants' conduct delayed and substantially diminished the sale of generic ACTOS and ACTO*plus* met in the United States. But for defendants' illegal conduct, generic drug manufacturers would have entered the market unimpeded and competed on the merits against ACTOS and ACTO*plus* met. Generic drug manufacturers of ACTOS would have competed as early as January 17, 2011. Generic drug manufacturers of ACTO*plus* met would have competed as early as February 25, 2011. And, once such entry occurred, true price competition would have followed. The defendants' conduct unlawfully delayed and diminished the savings that purchasers of ACTOS and ACTO*plus* met and their generic equivalents would have garnered from unimpaired generic competition, with the anticompetitive effect of unlawfully maintaining supra-competitive prices for ACTOS and ACTO*plus* met.

349. The defendants' conduct harmed plaintiffs and the direct purchaser class by depriving them of the most cost efficient means of distribution, *i.e.*, a marketplace in which brand and generic manufacturers make their decisions about challenging patents on the basis of the merits (or lack thereof) of the patent challenges, free from the influence of unlawful

[73] *See King Drug Co. of Florence, Inc. v SmithKline Beecham Corp.*, 791 F.3d 388, 402-403 (3d Cir. 2015).

payments and market allocation arrangements. Contrary to the purpose of the Hatch-Waxman Act, defendants' anticompetitive conduct enabled them to: (i) delay the entry of less expensive generic versions of ACTOS and ACTO*plus* met in the United States; (ii) fix, raise, maintain, or stabilize the price of ACTOS and ACTO*plus* met; and (iii) permit Takeda to maintain a monopoly in the United States market for ACTOS, ACTO*plus* met and its generic equivalents.

350. As a direct and proximate result of defendants' unlawful conduct, plaintiffs and the direct purchaser class have sustained (and will continue to sustain) substantial losses and damage to their business and property in the form of overcharges they paid for ACTOS and ACTO*plus* met and their generic equivalents, the exact amount of which will be proven at trial. If generic competitors had not been unlawfully prevented from entering the market earlier and competing in the relevant markets, direct purchasers, such as plaintiffs and members of the class, would have paid less for these drugs by (a) receiving discounts on their remaining brand purchases of these drugs, (b) substituting purchases of less-expense generic versions for their purchases of more-expensive brand versions, and/or (c) purchasing the generic versions of these drugs at lower prices sooner.

351. Absent Takeda's wrongful Orange Book listings of the '584 and '404 patents as covering the drug product ACTOS, numerous generic companies would have filed section viii statements to those patents in order to avoid any bar to final FDA approval of their ANDAs. Teva did in fact submit only a section viii statement as to these patents. And while the Ranbaxy and Actavis ANDAs had paragraph IV certifications as to those patents (given the wrongful product coverage claimed by Takeda), their ANDAs *also* indicated that the labels would carve-out the metformin and insulin uses; if their were no reason to paragraph IV certify, and since they had agreed to the limitation in any event, reasonable generic companies in the

position of Ranbaxy and Actavis would have simply submitted a section viii statement in response to the listing of those method of use only patents for ACTOS.

352. Among other consequences, if Takeda had not wrongfully caused the '584 and '404 patents to be listed, and maintained as listed, in the Orange Book as claiming the drug product ACTOS (as opposed to only methods of using it with metformin and insulin), no false exclusivity for ACTOS generics would have existed, and many generics would have filed section viii statements as to those patents. It is highly likely, if not a certainty, that the FDA would have granted at least Teva final FDA approval for its ACTOS ANDA on or about the end of January 2011. The FDA had already granted Teva tentative approval to its ANDA, and this meant that all issues (other than the expiry of the '777 patent) were acceptable. Given that Teva is the world's largest and most successful generic company, and that the large number of generic applicants here shows the product is not difficult to make, there is no reason to presume Teva would have experienced any setbacks in its ANDA since being granted tentative approval. And it is highly likely, if not a certainty, that upon FDA approval Teva would have entered the market with its generic ACTOS. The ACTOS market is blockbuster in size. Teva had repeatedly entered generic markets at the soonest opportunity following FDA ANDA approval. A reasonable generic company in the position of Teva would have entered immediately following FDA approval.

353. Without the false Orange Book listing, the resolutions of the cases with Mylan, Ranbaxy, Actavis and Teva would have looked materially different. And without below market rate authorized distributorships, or coordination clauses assuring each of the generic competitors that their launches were timed with the others, the resolutions would have looked materially different. Industry practice, applied microeconomics, the law of induced infringement claims for carved-out section viii filings and common sense teach that the entry

dates would have been on or shortly after the January/February 2011 time period for both products, and certainly earlier than was provided in the March and December 2010 pacts.

VII. CLASS ACTION ALLEGATIONS

354. Plaintiffs, on behalf of themselves and all direct purchaser class members, seeks damages, measured as overcharges, trebled, against defendants based on allegations of anticompetitive conduct in the market for ACTOS and ACTO*plus* met, and their AB-rated generic equivalents.

355. Plaintiffs bring this action under FED. R. CIV. P. 23(a) and (b)(3), on behalf of themselves and as the representative of a direct purchaser class defined as follows:

> All persons or entities in the United States and its territories and possessions, including the Commonwealth of Puerto Rico, who purchased ACTOS or its AB-rated generic equivalent from any one of the Defendants at any time on or after January 17, 2011 through and including the date that the anticompetitive effects of defendants' unlawful conduct cease (the "ACTOS class period"); and
>
> All persons or entities in the United States and its territories and possessions, including the Commonwealth of Puerto Rico, who purchased ACTO*plus* met or its AB-rated generic equivalent from any one of the Defendants at any time on or after February 25, 2011 through and including the date that the anticompetitive effects of defendants' unlawful conduct cease (the "ACTO*plus* met class period").

Excluded from the direct purchaser class are defendants and their officers, directors, management, employees, subsidiaries, or affiliates, and all governmental entities.

356. Members of the direct purchaser class are so numerous that joinder is impracticable. Plaintiffs believe that the class numbers in the many scores of entities. Further, the direct purchaser class is readily identifiable from information and records in defendants' possession.

357. Plaintiffs' claims are typical of those of each of the members of the direct purchaser class. Plaintiffs and each of the class members were damaged by the same wrongful conduct of defendants, *i.e.*, as a direct and proximate result of defendants' wrongful conduct, they paid artificially inflated prices for ACTOS and/or ACTO*plus* met and were deprived of the benefits of earlier and robust competition from cheaper generic versions of the products.

358. Plaintiffs will fairly and adequately protect and represent the interests of the direct purchaser class. Plaintiffs' interests are coincident with, and not antagonistic to, the interests of the direct purchaser class members.

359. Plaintiffs are represented by counsel with experience in prosecuting class action antitrust litigation, with particular experience in class action antitrust litigation involving pharmaceutical products.

360. Questions of law and fact common to the class members predominate over questions that may affect only individual class members, because defendants have acted on grounds generally applicable to the entire class, thereby making the recovery of overcharge damages with respect to the direct purchaser class as a whole appropriate. Such generally applicable conduct is inherent in defendants' wrongful conduct.

361. Questions of law and fact common to the direct purchaser class include, but are not limited to:

a. whether Takeda submitted false patent information describing the '584 Met Combo Patent and the '404 Insulin Combo Patent as claiming the ACTOS drug product;

b. whether Takeda violated Section 2 of the Sherman Act by causing the FDA to list, maintain and treat the '584 and '404 patents as covering the drug product ACTOS;

c. whether defendants conspired to willfully maintain and/or enhance Takeda's monopoly power over ACTOS and/or ACTO*plus* met, and their respective generic equivalents;

d. whether defendants conspired to suppress generic competition to ACTOS and/or ACTO*plus* met;

e. whether Takeda and Mylan, Teva, Ranbaxy and/or Actavis entered into unlawful agreements in restraint of trade;

f. whether, pursuant to such agreements in restraint of trade, Mylan, Teva, Ranbaxy, and/or Actavis agreed to delay their entry into the market with generic ACTOS;

g. whether, pursuant to such agreements in restraint of trade, Takeda paid Mylan, Teva, Ranbaxy, and/or Actavis;

h. whether Takeda's payments to Mylan, Teva, Ranbaxy, and Actavis were for a purpose other than delayed entry of generic ACTOS;

i. whether Takeda's payments to Mylan, Teva, Ranbaxy, and Actavis were necessary to yield a procompetitive benefit that is cognizable and non-pretextual;

j. whether the March and December 2010 pacts were unlawful under the rule of reason;

k. whether Takeda possessed market power or monopoly power over pioglitazone hydrochloride;

l. whether Takeda, Mylan, and/or Teva conspired to suppress generic competition to ACTO*plus* met;

m. whether, pursuant to such agreements in restraint of trade, Mylan and/or Teva agreed to delay their entry into the market with generic ACTO*plus* met;

n. whether Takeda's payments to Mylan and/or Teva were for a purpose other than delayed entry of generic ACTO*plus* met;

o. whether Takeda's payments to Mylan and/or Teva were necessary to yield a procompetitive benefit that is cognizable and non-pretextual;

p. whether Takeda possessed market power or monopoly power over pioglitazone hydrochloride and metformin hydrochloride;

q. whether Takeda possessed market power in the relevant market(s);

r. whether defendants' above-described conduct has substantially affected interstate and intrastate commerce;

s. whether, and to what extent, defendants' conduct caused antitrust injury (*i.e.*, overcharges) to plaintiffs and class members; and

t. the quantum of aggregate overcharge damages to plaintiffs and class members.

362. Class action treatment is the superior method for the fair and efficient adjudication of the controversy. Such treatment will permit a large number of similarly situated persons to prosecute their common claims in a single forum simultaneously, efficiently, and without the unnecessary duplication of evidence, effort, or expense that numerous individual actions would engender. The benefits of proceeding through the class mechanism, including providing injured persons or entities with a method for obtaining redress for claims that could not practicably be pursued individually, substantially outweigh potential difficulties in the management of this action as a class action.

363. Plaintiffs know of no special difficulty that would be encountered in this action that would preclude its maintenance as a class action.

364. Certification of the class is appropriate under FED. R. CIV. P. 23(b)(3) because the above common questions of law or fact predominate over any questions affecting individual class members, and a class action is superior to other available methods for the fair and efficient adjudication of this controversy.

365. Defendants' wrongful actions are generally applicable to the class members as a whole, for which plaintiffs seek, *inter alia*, damages and equitable remedies.

366. Absent a class action, defendants would retain the benefits of their wrongdoing despite their serious violations of the law and infliction of harm on plaintiffs and class members.

VIII. ANTITRUST IMPACT

367. During the relevant period, plaintiffs and members of the direct purchaser class purchased substantial amounts of ACTOS and ACTO*plus* met directly from Takeda and/or purchased substantial amounts of generic versions of ACTOS and ACTO*plus* met directly from generic manufacturers.

368. As a result of defendants' illegal conduct, members of the direct purchaser class were compelled to pay, and did pay, artificially inflated prices for their drug requirements on these purchases. Those prices were substantially greater than the prices that members of the direct purchaser class would have paid absent the illegal conduct alleged herein, because: (1) the price of ACTOS and ACTO*plus* met was artificially inflated by defendants' illegal conduct; (2) direct purchaser class members were deprived of the opportunity to purchase lower-priced generic versions of ACTOS and ACTO*plus* met sooner; and/or (3) the price of generic ACTOS and ACTO*plus* met was artificially inflated by defendants' illegal conduct.

369. As a consequence, plaintiffs and members of the direct purchaser class have sustained substantial losses and damage to their business and property in the form of overcharges. The full amount and forms and components of such damages will be calculated after discovery and upon proof at trial.

IX. IMPACT ON INTERSTATE COMMERCE

370. At all relevant times, Takeda manufactured, promoted, distributed, and sold substantial amounts of ACTOS and ACTO*plus* met in a continuous and uninterrupted flow of commerce across state and national lines throughout the United States.

371. At all material times, defendants transmitted funds, as well as contracts, invoices and other forms of business communications and transactions, in a continuous and uninterrupted flow of commerce across state and national lines in connection with the sale of ACTOS and ACTO*plus* met and their generic equivalents.

372. In furtherance of their efforts to monopolize and restrain competition, defendants employed the United States mails and interstate and international telephone lines, as well as means of interstate and international travel. Defendants' activities were within the flow of, and have substantially affected (and will continue to substantially effect), interstate commerce.

X. MONOPOLY POWER AND MARKET DEFINITION REGARDING ACTOS

373. Takeda wrongfully acquired and used market power over the market for ACTOS.

374. At all relevant times, Takeda had market power over ACTOS and its generic equivalents because it had the power to maintain the price of ACTOS at supracompetitive levels without losing so many sales as to make the supracompetitive price unprofitable. This market power may be shown directly, and therefore no relevant market needs to be defined.

375. A small, but significant, non-transitory price increase above the competitive level for ACTOS by Takeda would not have caused a loss of sales sufficient to make the price increase unprofitable.

376. ACTOS does not exhibit significant, positive cross-elasticity of demand with respect to price with any product other than AB-rated generic versions of ACTOS. Other oral Type 2 diabetes medicines are not AB-rated to ACTOS, cannot be automatically substituted for

ACTOS by pharmacists, do not exhibit substantial cross-price elasticity of demand with respect to ACTOS, and thus, are not economic substitutes for ACTOS.

377. ACTOS is not reasonably interchangeable with any products other than AB-rated generic versions of ACTOS.

378. ACTOS is part of the Type 2 diabetes drug class called thiazolidinediones. Thiazolidinediones, like a few other antidiabetic classes of drugs, are often referred to as "insulin sensitivity enhancers" due to their ability to decrease the body's resistance to insulin. Unique to thiazolidinediones, however, is that they increase certain levels of proteins – those that are more sensitive to insulin – and thus are the primary means by which a patient's blood sugar levels may be lowered. Due to their differing effect within the body, thiazolidinediones are significantly unique in their efficacy, safety, and side effect profile. These attributes play a critical role in doctors' selection of the most appropriate antidiabetic for a particular patient.

379. Due to, among other reasons, doctors' perception of ACTOS's lower association with heart failure, death, and liver toxicity, ACTOS is significantly differentiated from other drugs in the thiazolidinedione class. For these and other clinical reasons, substantial numbers of doctors prefer ACTOS to other thiazolidinedione drugs (*e.g.*, Avandia (rosiglitazone)). For example, according to some studies patients aged 65 and older who take Avandia (rosiglitazone) have a higher rate of death and a greater risk of heart failure when compared with similar patients taking ACTOS.

380. Functional similarities between ACTOS and non-ACTOS thiazolidinedione products are insufficient to permit inclusion of those other thiazolidinedione products in the relevant market with ACTOS. To be an economic substitute for antitrust purposes, a functionally similar product must also exert sufficient pressure on the prices and sales of

another product, so that the price of that product cannot be maintained above levels that would be maintained in a competitive market. No other thiazolidinedione product (except for AB-rated generic ACTOS) will take away sufficient sales from ACTOS to prevent Takeda from raising or maintaining the price of ACTOS above levels that would prevail in a competitive market.

381. At all relevant times, the existence of other products designed to treat adults with Type 2 diabetes did not significantly constrain Takeda's pricing of ACTOS. At all relevant times, Takeda's price for ACTOS was at least 60% above its marginal cost of production and at least 40% above its marginal cost including marketing costs. Takeda never lowered the price of ACTOS in response to the pricing of other branded treatments for Type 2 diabetes (or the generic versions of such medications).

382. Takeda needed to control only ACTOS and its AB-rated generic equivalents, and no other products, to profitably maintain the price of ACTOS at supracompetitive levels. Only the market entry of a competing, AB-rated generic version of ACTOS would have rendered Takeda unable to profitably maintain supracompetitive prices for ACTOS.

383. Takeda knew that entry of a generic version of ACTOS would be a uniquely significant market event. Takeda predicted that, unlike the entry of other branded treatments for Type 2 diabetes (or the generic versions of such medications), entry of generic ACTOS would take substantial unit sales from Takeda. For example, ACTOS did not lose substantial sales when generic versions of other branded Type 2 diabetes drugs entered the market at low prices. But Takeda predicted that entry of generic ACTOS would immediately cause branded ACTOS to lose well more than half of its unit sales. Likewise, Mylan, Ranbaxy, Actavis, and Teva estimated that their generic versions of ACTOS would take essentially all of their sales

away from branded ACTOS and few, if any, sales from other branded Type 2 diabetes drugs (or generic versions of such medications).

384. Takeda, Mylan, Teva, Ranbaxy, and Actavis predicted that the competitive impact of generic ACTOS products would be substantial. Among other things, defendants predicted that the availability of generic ACTOS would deliver well more than a billion dollars of savings to consumers.

385. At all relevant times, Takeda sold ACTOS at prices well in excess of its marginal costs and the ACTOS competitive price, and enjoyed the resulting high profit margins and corresponding financial benefits—to the financial detriment of plaintiffs and the ACTOS class members.

386. Takeda had, and exercised, the power to exclude and restrict competition to ACTOS and its AB-rated bioequivalents.

387. Takeda, at all relevant times, enjoyed high barriers to entry with respect to competition in the relevant product market due to patent and other regulatory protections, as well as the high cost of entry and expansion.

388. To the extent plaintiffs are legally required to prove monopoly power circumstantially by first defining a relevant product market, plaintiffs allege that the relevant product market is oral pioglitazone hydrochloride for the treatment of adults with Type 2 diabetes (*i.e.*, ACTOS and its AB-rated generic equivalents). At all relevant times, Takeda profitably maintained the price of pioglitazone hydrochloride well above competitive levels.

389. The relevant geographic market is the United States and its territories.

390. At all relevant times prior to generic entry, Takeda's market share in the relevant geographic market was 100%, confirming its monopoly power. Takeda continued to possess substantial market share and market power after generic entry.

XI. MARKET POWER AND MARKET DEFINITION REGARDING ACTO*PLUS* MET

391. Takeda wrongfully acquired and used market power over the markets for ACTO*plus* met.

392. At all relevant times, Takeda had market power over ACTO*plus* met and its generic equivalents because it had the power to maintain the price of ACTO*plus* met at supracompetitive levels without losing so many sales as to make the supracompetitive price unprofitable. This market power may be shown directly, and therefore no relevant market needs to be defined.

393. At all relevant times, a small, but significant, non-transitory price increase above the competitive level for ACTO*plus* met by Takeda would not have caused a loss of sales sufficient to make the price increase unprofitable.

394. At competitive price levels ACTO*plus* met did not exhibit significant, positive cross-elasticity of demand with respect to price with any product other than AB-rated generic versions of ACTO*plus* met. Other oral Type 2 diabetes medicines are not AB-rated to ACTO*plus* met, cannot be automatically substituted for ACTO*plus* met by pharmacists, do not exhibit substantial cross-price elasticity of demand with respect to ACTO*plus* met, and thus, are not economic substitutes for ACTO*plus* met.

395. ACTO*plus* met is not reasonably interchangeable with any products other than AB-rate generic versions of ACTO*plus* met.

396. For clinical reasons, ACTO*plus* met is sufficiently unique from other Type 2 diabetes drugs as it is specifically targeted to, and taken by, patients who have not sufficiently improved their blood sugar levels by taking either metformin or pioglitazone alone.

397. Functional similarities between ACTO*plus* met and non-ACTO*plus* met Type 2 diabetes drug products are insufficient to permit inclusion of those other Type 2 diabetes drug products in the relevant market with ACTO*plus* met. To be an economic substitute for antitrust purposes, a functionally similar product must also exert sufficient pressure on the prices and sales of another product, so that the price of that product cannot be maintained above levels that would be maintained in a competitive market. No other Type 2 diabetes drug product (except for AB-rated generic ACTO*plus* met) will take away sufficient sales from ACTO*plus* met to prevent Takeda from raising or maintaining the price of ACTO*plus* met above levels that would prevail in a competitive market.

398. At all relevant times, the existence of other products designed to treat adults with Type 2 diabetes did not significantly constrain Takeda's pricing of ACTO*plus* met. At all relevant times, Takeda's price for ACTO*plus* met was at least 60% above its marginal cost of production and at least 40% above its marginal cost, including marketing costs. Takeda never lowered the price of ACTO*plus* met in response to the pricing of other branded treatments for Type 2 diabetes (or the generic versions of such medications).

399. Takeda needed to control only ACTO*plus* met and its AB-rated generic equivalents, and no other products, to profitably maintain the price of ACTO*plus* met at supracompetitive levels. Only the market entry of a competing, AB-rated generic version of ACTO*plus* met would have rendered Takeda unable to profitably maintain supracompetitive prices for ACTO*plus* met.

400. Takeda knew that entry of a generic version of ACTO*plus* met would be a uniquely significant market event. Takeda predicted that unlike the entry of other branded treatments for Type 2 diabetes (or the generic versions of such medications), entry of generic ACTO*plus* met would take substantial unit sales from Takeda. For example, ACTO*plus* met did not lose substantial sales when generic versions of other branded type 2 diabetes drugs entered the market at low prices. But Takeda predicted that entry of generic ACTO*plus* met would immediately cause branded ACTO*plus* met to lose well more than half of its unit sales. Likewise, Mylan and Teva estimated that their generic versions of ACTO*plus* met would take essentially all of their sales away from branded ACTO*plus* met and few, if any, sales from other branded Type 2 diabetes drugs (or generic versions of such medications).

401. Takeda, Mylan, and Teva predicted the competitive impact of generic ACTO*plus* met products would be substantial. Among other things, defendants predicted that the availability of generic ACTO*plus* met would deliver hundreds of millions of dollars of savings to consumers.

402. At all relevant times, Takeda sold ACTO*plus* met at prices well in excess of its marginal costs and ACTO*plus* met's competitive price, and enjoyed the resulting high profit margins and corresponding financial benefits—to the financial detriment of plaintiffs and the ACTO*plus* met class members.

403. Takeda had, and exercised, the power to exclude and restrict competition to ACTO*plus* met and its AB-rated bioequivalents.

404. Takeda, at all relevant times, enjoyed high barriers to entry with respect to competition in the relevant product market due to patent and other regulatory protections, as well as the high cost of entry and expansion.

405. To the extent plaintiffs are legally required to prove market power circumstantially by first defining a relevant product market, plaintiffs allege that the relevant product market is a fixed unit dose of oral pioglitazone hydrochloride and biguanide for the treatment of adults with Type 2 diabetes (*i.e.*, ACTO*plus* met and its AB-rated generic equivalents). During all relevant times, Takeda profitably maintained the price of ACTO*plus* met well above competitive levels.

406. The relevant geographic market is the United States and its territories.

407. At all relevant times prior to generic entry, Takeda's market share in the relevant geographic market was 100%, confirming its market power. Takeda continued to possess substantial market share and market power after generic entry.

XII. MARKET EFFECTS AND DAMAGES TO THE CLASSES

408. But for the anticompetitive conduct alleged above, generic competition for ACTOS would have begun as early as January 17, 2011, and generic competition for ACTO*plus* met would have begun as early as February 25, 2011.

409. Defendants' anticompetitive conduct had the purpose and effect of restraining competition unreasonably and injuring competition by protecting ACTOS and ACTO*plus* met from generic competition. Defendants' unlawful conduct was designed to, and did, discourage rather than encourage competition on the merits. Such conduct was undertaken for the anticompetitive purpose of forestalling generic competition.

410. Defendants' exclusionary conduct delayed generic competition, and unlawfully allowed Takeda to sell its branded drug products free from competition. But for this wrongful conduct, one or more generic competitor would have begun marketing AB-rated generic versions of these drugs much sooner than they actually were marketed.

411. Other generic manufacturers seeking to sell AB-rated generic versions of ACTOS and ACTO*plus* met, including Mylan, Teva, Actavis, and Ranbaxy all had extensive experience in the pharmaceutical industry, including in obtaining approval for ANDAs and marketing generic pharmaceutical products, and at least several of these generic manufacturers would have been ready, willing and able to effectuate earlier launches of their generic versions, were it not for defendants illegal and unlawful acts and conspiracies.

412. Defendants' unlawful actions and anticompetitive conduct allowed Takeda to maintain a monopoly and exclude competition in the markets for ACTOS and ACTO*plus* met, and their generic equivalents, and to maintain supracompetitive prices for both ACTOS and ACTO*plus* met, to the detriment of plaintiffs and the members of the direct purchaser class. Defendants' anticompetitive conduct delayed and impaired generic competition and unlawfully enabled Takeda to sell ACTOS and ACTO*plus* met without timely generic competition.

413. Typically, generic drugs are initially priced significantly below the corresponding branded drug to which they are AB-rated. As a result, upon generic entry, direct purchasers rapidly substitute generic versions of a branded drug for some or all of their purchases. As more generic drug manufacturers enter the market, prices for generic versions of a branded drug predictably plunge even further due to competition between the generic drug manufacturers, and, correspondingly, the branded drug loses even more market share to the generics.

414. This price competition enables all purchasers of the drug to (i) purchase generic versions of a drug at substantially lower prices, (ii) purchase generic equivalents of the drug at a lower price, sooner, and (iii) purchase the branded drug at a reduced price. Consequently, branded drug manufacturers have a keen financial interest in delaying and impairing the onset

of generic drug competition, which, in turn causes purchasers to experience substantial increases in costs.

415. If generic competitors had not been unlawfully prevented from entering the market earlier and competing in the relevant markets by the defendants anticompetitive conduct, direct purchasers, such as plaintiffs and members of the class, would have paid less for these drugs by (i) receiving discounts on their remaining brand purchases of ACTOS and *ACTOplus* met; (ii) substituting less-expensive AB-rated generic ACTOS and/or ACTO*plus* met for the more expensive branded ACTOS and/or ACTO*plus* met, and/or (iii) purchasing generic ACTOS and/or ACTO*plus* met at lower prices sooner.

416. Moreover, due to defendants' anticompetitive conduct, other generic drug manufacturers were discouraged from and/or delayed in (i) developing and marketing their own generic versions of ACTOS and/or ACTO*plus* met, and/or (ii) challenging the validity or infringement of Takeda's patents in court.

417. At all relevant times during the class period, plaintiffs and the direct purchaser class members directly purchased substantial amounts of ACTOS and/or ACTO*plus* met. As a direct and proximate result of defendants' illegal conduct, plaintiffs and the direct purchaser class members were compelled to pay, and did pay, artificially inflated prices for ACTOS and/or ACTO*plus* met and their generic equivalents.

418. As a direct and proximate result of defendants' unlawful anticompetitive scheme and wrongful conduct, plaintiffs and the direct purchaser class members have sustained (and will continue to sustain) substantial losses and damage to their business and property in the form of overcharges they paid for ACTOS and/or ACTO*plus* met and their generic equivalents, the exact amount of which will be proven at trial.

419. Defendants' unlawful conduct deprived plaintiffs and the direct purchaser class members of the benefits of competition that the antitrust laws were designed to ensure.

XIII. CLAIMS FOR RELIEF

CLAIM I: VIOLATION OF 15 U.S.C. § 2 MONOPOLIZATION AND MONOPOLISTIC SCHEME (Against Takeda)

420. Plaintiffs hereby incorporate each preceding and succeeding paragraph as though fully set forth herein.

421. At all relevant times, Takeda possessed substantial market power (i.e., monopoly power) in the relevant market. Takeda possessed the power to control prices in, prevent prices from falling in, and exclude competitors from the relevant market.

422. Through its overarching anticompetitive scheme, Takeda willfully maintained its monopoly power in the relevant market using restrictive or exclusionary conduct, rather than by means of greater business acumen, and thereby injured plaintiffs and the class.

423. It was Takeda's conscious object to further its dominance in the relevant market by and through the overarching anticompetitive scheme.

424. The natural and probable consequence of Takeda's overarching anticompetitive scheme, which was intended by it and plainly foreseeable to it, was to control prices and exclude competition in the relevant market.

425. There was a substantial and real chance, a reasonable likelihood, and/or a dangerous probability that Takeda would succeed in and achieve its goal of maintaining monopoly power in the relevant market.

426. Takeda's scheme harmed competition.

427. There is and was no cognizable, non-pretextual procompetitive justification for Takeda's actions comprising the anticompetitive scheme that outweighs the scheme's harmful effects. Even if there were some conceivable such justification that Takeda were permitted to assert, the scheme is and was broader than necessary to achieve such a purpose.

428. As a direct and proximate result of Takeda's illegal and monopolistic conduct, as alleged herein, plaintiffs and the class were harmed.

CLAIM II: VIOLATION OF 15 U.S.C. § 1
CONSPIRACY TO MONOPOLIZE
(Against all defendants)

429. Plaintiffs hereby incorporate each preceding and succeeding paragraph as though fully set forth herein.

430. At all relevant times, Takeda possessed substantial market power (i.e., monopoly power) in the relevant market. Takeda possessed the power to control prices in, prevent prices from falling in, and exclude competitors from the relevant market.

431. Through the overarching anticompetitive scheme, including the agreements (and attendant payments) between Takeda, on the one hand, and Mylan, Actavis, Ranbaxy, and Teva on the other, the defendants conspired to maintain Takeda's monopoly power in the relevant market in order to block and delay market entry of AB-rated generic versions of ACTOS and ACTO*plus* met. The unlawful agreements between Takeda and the generic defendants allocated all sales of ACTOS and ACTO*plus* met and their AB-rated generic equivalents in the United States to Takeda; delayed the sales of generic ACTOS and ACTO*plus* met products; and fixed the price at which plaintiffs and members of the class would pay for ACTOS and ACTO*plus* met and/or their AB-rated generic equivalents at the higher, branded price.

432. The goal, purpose and/or effect of the conspiracy was to maintain and extend Takeda's monopoly power in the United States market for pioglitazone hydrochloride tablets and for the fixed dose combination product containing both pioglitazone hydrochloride and metformin in violation of Sherman Act Section 1, 15 U.S.C. § 1. The conspiracy prevented and/or delayed generic competition to ACTOS and ACTO*plus* met and enabled Takeda to continue charging supracompetitive prices for ACTOS and ACTO*plus* met without a substantial loss of sales.

433. Defendants knowingly and intentionally conspired to maintain and enhance Takeda's monopoly power in the relevant market.

434. Defendants specifically intended that their conspiracy would maintain Takeda's monopoly power in the relevant market, and injured American Sales and the class thereby.

435. Each defendant committed at least one overt act in furtherance of the conspiracy, including:

- Takeda paid each generic defendant to stay off the market.
- Each of Mylan, Actavis, Ranbaxy, and Teva agreed to stay out of the market for pioglitazone hydrochloride tablets until August 17, 2012.
- Takeda on the one hand, and each of Mylan, Actavis, and Ranbaxy on the other, all agreed that if another generic manufacturer launched a generic version of ACTOS before August 17, 2012, then Mylan, Actavis, and Ranbaxy could also immediately come to market.
- Each of Mylan, Actavis, and Ranbaxy agreed to drop their patent challenges, including any efforts to break the bottleneck created by the listing of the Takeda patents in the Orange Book and the unlawful agreements.
- Teva agreed to stay out of the market for the fixed dose combination product containing both pioglitazone hydrochloride and metformin until the date on which Mylan entered.

436. As a direct and proximate result of the defendants' concerted conduct, as alleged herein, plaintiffs and the class were injured.

CLAIM III: VIOLATION OF 15 U.S.C. § 2
CONSPIRACY TO MONOPOLIZE
(Against each, some, and/or all defendants)

437. Plaintiffs hereby incorporate each preceding and succeeding paragraph as though fully set forth herein.

438. Through the overarching anticompetitive scheme defendants conspired to maintain Takeda's monopoly power in the relevant market in order to block and delay market entry of pioglitazone hydrochloride, *i.e.*, AB-rated generic versions of Actos. The unlawful Exclusion Payment Agreements allocated all sales of pioglitazone hydrochloride in the United States to Takeda; delayed sales of generic Actos; and fixed the price at which Plaintiffs and members of the Class would pay for pioglitazone hydrochloride at both the higher, branded price, and at the higher generic price (resulting from the delay of generic entry); delayed and allocated all sales of generic Actos in the United States to the generic defendants.

439. The goal, purpose and/or effect of the anticompetitive scheme, detailed above, including the Exclusion Payment Agreements was to maintain and extend Takeda's monopoly power in the United States market for pioglitazone hydrochloride in violation of 15 U.S.C. § 2. The Exclusion Payment Agreement prevented and/or delayed generic competition to Actos and enabled Takeda to continue charging supracompetitive prices for Actos without a substantial loss of sales.

440. Defendants knowingly and intentionally conspired to maintain and enhance Takeda's monopoly power in the relevant market.

441. Each defendant committed at least one over act in furtherance of the conspiracy.

442. Defendants specifically intended their conspiracy, including its Exclusion Payment Agreements, to extend Takeda's monopoly power in the relevant market, and directly and proximately injured Plaintiff and class members thereby.

CLAIM IV: VIOLATION OF 15 U.S.C. § 1
AGREEMENT RESTRAINING TRADE
(Against Takeda and Mylan)

443. Plaintiffs hereby incorporate each preceding and succeeding paragraph as though fully set forth herein.

444. Defendants Takeda and Mylan have engaged, and continue to engage, in an unlawful contract, combination or conspiracy that has unreasonably restrained trade or commerce in violation of Section 1 of the Sherman Act, 15 U.S.C. § 1.

445. On or about March 15, 2010 and at times prior to the formal execution thereof, Takeda and Mylan entered into the March 2010 pact, a continuing illegal contract, combination and conspiracy in restraint of trade under which Takeda agreed to pay Mylan substantial consideration in exchange for Mylan's agreement to delay bringing its generic versions of ACTOS and ACTO*plus* met to the market, the purpose and effect of which were to: (a) allocate 100% of the market for ACTOS and ACTO*plus* met products in the United States to Takeda; (b) prevent the sale of generic versions of ACTOS and ACTO*plus* met in the United States, thereby protecting ACTOS and ACTO*plus* met from generic competition; (c) fix the price at which direct purchasers would pay for ACTOS and ACTO*plus* met products at supracompetitive levels; (d) allocate a substantial portion of United States generic ACTOS and ACTO*plus* met sales to Mylan during the first 180 days of generic sales; and (e) allow Mylan the ability to immediately enter the ACTO*plus* met market on a date certain if either (i) branded

sales dipped below a specified threshold as soon or (ii) any other generic manufacturer brought a generic version of ACTO*plus* met to market.

446. The March and December 2010 pacts harmed plaintiffs and the class as set forth above.

447. The March 2010 pact covered a sufficiently substantial percentage of the relevant market to harm competition.

448. Takeda and Mylan are *per se* liable for the Mylan Exclusion Payment Agreement or are liable under a "quick look" or rule of reason standard.

449. The agreement between and among Takeda and Mylan and their conduct under the Mylan Exclusion Payment Agreement is an illegal restraint of trade or commerce and a continuing violation of the Sherman Act. There is and was no legitimate, nonpretextual, procompetitive business justification for the exclusion payment that outweighs its harmful effect. Even if there were some conceivable justification, the payment was not necessary to achieve such a purpose, nor was it the least restrictive means of achieving any such purported justification.

450. As a direct and proximate result of Takeda's and Mylan's anticompetitive conduct, as alleged herein, plaintiffs and the class were harmed and have sustained substantial losses and damage to their business and property in the form of overcharges as set forth above.

CLAIM V: VIOLATION OF 15 U.S.C. § 1
AGREEMENT RESTRAINING TRADE
(Against Takeda and Actavis)

451. Plaintiffs hereby incorporate each preceding and succeeding paragraph as though fully set forth herein.

452. Defendants Takeda and Actavis have engaged, and continue to engage, in an unlawful contract, combination or conspiracy that has unreasonably restrained trade or commerce in violation of Section 1 of the Sherman Act, 15 U.S.C. § 1.

453. On or about March 15, 2010 and at times prior to the formal execution thereof, Takeda and Actavis entered into the Actavis Exclusion Payment Agreement, a continuing illegal contract, combination and conspiracy in restraint of trade under which Takeda agreed to pay Actavis substantial consideration in exchange for Actavis's agreement to delay bringing its generic version of ACTOS to the market, the purpose and effect of which were to: (a) allocate 100% of the market for ACTOS and ACTO*plus* met products in the United States to Takeda; (b) prevent the sale of generic versions of ACTOS and ACTO*plus* met in the United States, thereby protecting ACTOS and ACTO*plus* met from generic competition for five years or more; (c) fix the price at which direct purchasers would pay for ACTOS and ACTO*plus* met products at supracompetitive levels; and (d) allocate a substantial portion of United States generic ACTOS and ACTO*plus* met sales to Actavis during the first 180 days of generic sales.

454. The Actavis Exclusion Payment Agreement harmed plaintiffs and the class as set forth above.

455. The Actavis Exclusion Payment Agreement covered a sufficiently substantial percentage of the relevant market to harm competition.

456. Takeda and Actavis are *per se* liable for the Actavis Exclusion Payment Agreement or are liable under a "quick look" or rule of reason standard.

457. The agreement between and among Takeda and Actavis and their conduct under the Actavis Exclusion Payment Agreement is an illegal restraint of trade or commerce and a continuing violation of the Sherman Act. There is and was no legitimate, nonpretextual,

procompetitive business justification for the exclusion payment that outweighs its harmful effect. Even if there were some conceivable justification, the payment was not necessary to achieve such a purpose, nor was it the least restrictive means of achieving any such purported justification.

458. As a direct and proximate result of Takeda's and Actavis's anticompetitive conduct, as alleged herein, plaintiffs and the class were harmed and have sustained substantial losses and damage to their business and property in the form of overcharges as set forth above.

CLAIM VI: VIOLATION OF 15 U.S.C. § 1
AGREEMENT RESTRAINING TRADE
(Against Takeda and Ranbaxy)

459. Plaintiffs hereby incorporate each preceding and succeeding paragraph as though fully set forth herein.

460. Defendants Takeda and Ranbaxy have engaged, and continue to engage, in an unlawful contract, combination or conspiracy that has unreasonably restrained trade or commerce in violation of Section 1 of the Sherman Act, 15 U.S.C. § 1.

461. On or about March 15, 2010 and at times prior to the formal execution thereof, Takeda and Ranbaxy entered into the Ranbaxy Exclusion Payment Agreement, a continuing illegal contract, combination and conspiracy in restraint of trade under which Takeda agreed to pay Ranbaxy substantial consideration in exchange for Ranbaxy's agreement to delay bringing its generic version of ACTOS met to the market, the purpose and effect of which were to: (a) allocate 100% of the market for ACTOS and ACTO*plus* met products in the United States to Takeda; (b) prevent the sale of generic versions of ACTOS and ACTO*plus* met in the United States, thereby protecting ACTOS and ACTO*plus* met from generic competition; (c) fix the price at which direct purchasers would pay for ACTOS and ACTO*plus* met products at

supracompetitive levels; and (d) allocate a substantial portion of United States generic ACTOS and ACTO*plus* met sales to Ranbaxy during the first 180 days of generic sales.

462. The Ranbaxy Exclusion Payment Agreement harmed plaintiffs and the class as set forth above.

463. The Ranbaxy Exclusion Payment Agreement covered a sufficiently substantial percentage of the relevant market to harm competition.

464. Takeda and Ranbaxy are *per se* liable for the Ranbaxy Exclusion Payment Agreement or are liable under a "quick look" or rule of reason standard.

465. The agreement between and among Takeda and Ranbaxy and their conduct under the Ranbaxy Exclusion Payment Agreement is an illegal restraint of trade or commerce and a continuing violation of the Sherman Act. There is and was no legitimate, nonpretextual, procompetitive business justification for the exclusion payment that outweighs its harmful effect. Even if there were some conceivable justification, the payment was not necessary to achieve such a purpose, nor was it the least restrictive means of achieving any such purported justification.

466. As a direct and proximate result of Takeda's and Ranbaxy's anticompetitive conduct, as alleged herein, plaintiffs and the class were harmed and have sustained substantial losses and damage to their business and property in the form of overcharges as set forth above.

CLAIM VIII: VIOLATION OF 15 U.S.C. § 1
AGREEMENT RESTRAINING TRADE
(Against Takeda and Teva)

467. Plaintiffs hereby incorporate each preceding and succeeding paragraph as though fully set forth herein.

468. Defendants Takeda and Teva have engaged, and continue to engage, in an unlawful contract, combination or conspiracy that has unreasonably restrained trade or commerce in violation of Section 1 of the Sherman Act, 15 U.S.C. § 1.

469. On or about December 22, 2010 and at times prior to the formal execution thereof, Takeda and Teva entered into the Teva Exclusion Payment Agreement, a continuing illegal contract, combination and conspiracy in restraint of trade under which Takeda agreed to pay Teva substantial consideration in exchange for Teva's agreement to delay bringing its generic version of ACTOS and ACTO*plus* met to the market, the purpose and effect of which were to: (a) allocate 100% of the market for ACTOS and ACTO*plus* met products in the United States to Takeda; (b) prevent the sale of generic versions of ACTOS and ACTO*plus* met in the United States, thereby protecting ACTOS and ACTO*plus* met from generic competition for five years or more; (c) fix the price at which direct purchasers would pay for ACTOS and ACTO*plus* met products at supracompetitive levels; and (d) allocate a substantial portion of United States generic ACTO*plus* met sales to Ranbaxy during the first 180 days of generic sales.

470. The Teva Exclusion Payment Agreement harmed plaintiffs and the class as set forth above.

471. The Teva Exclusion Payment Agreement covered a sufficiently substantial percentage of the relevant market to harm competition.

472. Takeda and Teva are *per se* liable for the Teva Exclusion Payment Agreement or are liable under a "quick look" or rule of reason standard.

473. The agreement between and among Takeda and Teva and their conduct under the Teva Exclusion Payment Agreement is an illegal restraint of trade or commerce and a continuing violation of the Sherman Act. There is and was no legitimate, nonpretextual,

procompetitive business justification for the exclusion payment that outweighs its harmful effect. Even if there were some conceivable justification, the payment was not necessary to achieve such a purpose, nor was it the least restrictive means of achieving any such purported justification.

474. As a direct and proximate result of Takeda's and Teva's anticompetitive conduct, as alleged herein, plaintiffs and the class were harmed and have sustained substantial losses and damage to their business and property in the form of overcharges as set forth above.

XIV. DEMAND FOR JUDGMENT

WHEREFORE, ASC and CCI, on behalf of themselves and the class, respectfully request that the Court:

A. Determine that this action may be maintained as a class action pursuant to Fed. R. Civ. P. 23(a) and (b)(3), and direct that reasonable notice of this action, as provided by Fed. R. Civ. P. 23(c)(2), be given to the class, and declare ASC as a representative of the class;

B. Enter joint and several judgments against the defendants and in favor of ASC and the class;

C. Award the class damages (*i.e.*, three times overcharges) in an amount to be determined at trial, plus interest in accordance with law;

D. Award ASC, CCI, and the class their costs of suit, including reasonable attorneys' fees as provided by law; and

E. Award such further and additional relief as is necessary to correct for the anticompetitive market effects caused by the defendants' unlawful conduct, as the Court may deem just and proper under the circumstances.

XV. JURY DEMAND

Pursuant to Fed. R. Civ. P. 38, ASC and CCI, on behalf of themselves and the proposed class, demand a trial by jury on all issues so triable.

Dated: January 7, 2016

Respectfully Submitted,

/s/ Thomas M. Sobol

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CERTIFICATE OF SERVICE

I, Thomas M. Sobol, hereby certify that I caused a copy of the foregoing to be filed electronically via the Court's electronic filing system. Those attorneys who are registered with the Court's electronic filing system may access these filings through the Court's system, and notice of these filings will be sent to these parties by operation of the Court's electronic filing system.

Dated: January 7, 2016

/s/ Thomas M. Sobol
Thomas M. Sobol